CHEMICAL BIOLOGICAL DEFENSE PROGRAM

Technology Transition Handbook

JOINT CHEMICAL BIOLOGICAL DEFENSE PROGRAM

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Technology Transition Handbook

1. Purpose. This Handbook sets forth guidelines and procedures to facilitate the smooth, effective and timely transition of technologies and technical information developed by Science and Technology (S&T) projects from the Joint Science and Technology Office (JSTO) to the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) Joint Project Manager (JPM).
2. Applicability. This handbook applies to the JPEO-CBD and the JSTO. It also applies to other agencies preparing and submitting science and technology efforts for transition into the Joint Chemical and Biological Defense Program.
3. Releasability. This Handbook is approved for public release; distribution is unlimited. Department of Defense (DoD) components (to include the combatant commands), other federal agencies, and the public may obtain copies of this manual through the JPEO-CBD or the JSTO.
4. Effective Date. This Handbook is effective upon receipt.

COL, USA

CHARLES R. GALLAWAY
Director
Joint Science and Technology Office
for Chemical and Biological Defense

STEPHEN V. REEVES
Brigadier General, USA
Joint Program Executive Officer
for Chemical and Biological Defense

Prepared by the
Joint Program Executive Office for Chemical and Biological Defense and Joint Science and Technology Office
20 July 2005

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Introduction

The purpose of this handbook is to provide guidance and establish procedures to facilitate the smooth, effective, and timely transition of technologies and technical information developed by Science and Technology (S&T) projects from the Joint Science and Technology Office (JSTO) to the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) Joint Project Manager (JPM). Transition into acquisition programs/programs of record will be accomplished by "leveraging the best technology available from both government and commercial sources" to "rapidly transition technology into new material systems" to reduce or resolve warfighter capability gaps. A key enabler for evolutionary acquisition and reduced cycle time is to have technology that is sufficiently mature to be fielded in a relatively short time.

This document provides guidance for the transition of all defense science and technology base systems and components, Defense Technology Objective (DTO) Programs, and Advanced Concept Technology Demonstrations (ACTD) executed within or transitioned into the Chemical Biological Defense Program (CBDP). It also encompasses S&T programs and unsolicited proposals from other DoD agencies and non-governmental organizations assimilated into the JSTO developmental process.

Background

Prior to the CBDP Implementation Plan (Under Secretary of Defense for Acquisition Technology and Logistics (USD (AT&L)), April 2003), advisors to the Office of the Secretary of Defense concluded that the CBDP S&T base was not necessarily aligned with the warfighter's needs, contributing to a perception of too little return on investment. As a result, the use of management incentive tools was encouraged and the development of processes was initiated that would facilitate the transition of technologies out of research and development to the acquisition community. The CBDP Implementation Plan has established the framework for the JPEO-CBD and the JSTO to develop processes to positively effect the transition of technologies from S&T to acquisition in order to meet the needs of the warfighter. This handbook documents those processes and tools necessary to accomplish that goal.

Scope

This handbook addresses the processes for transition of technology and technical information from the JSTO to the JPEO-CBD, from DoD and other government agencies (i.e. the Defense Advanced Research Projects Agency (DARPA), Department of Homeland Security (DHS), etc.), as well as non-governmental agencies (industry and academia) through the JSTO to JPEO-CBD. This handbook will address: 1) the technology transition process supporting the development of an acquisition strategy by the JPEO-CBD JPM, 2) the development of S&T program transition exit criteria, Technology Readiness Levels (TRL), and the documentation of such in a Technology Transition Agreement (TTA), 3) the process for Technology Readiness Evaluations (TRE) and Technology Readiness Assessments (TRA), and 4) the conduct of the Transition Quarterly Review (TQR).

This handbook is intended to be used by the JPMs, the JSTO Capability Area Project Officers (CAPOs), the Joint Test and Evaluation (T&E) Executive, and the Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense (JRO-CBRND) as appropriate for the documentation of T&E capabilities in the transition process and the conduct of the TQR.

Responsibilities

The Implementation Plan for the Management of the CBDP assigns two agencies with primary responsibility for managing the transition of emerging technologies in the CBDP: the JSTO and the JPEO-CBD. Figures 1 and 2 depict the JSTO and JPEO-CBD organizations.

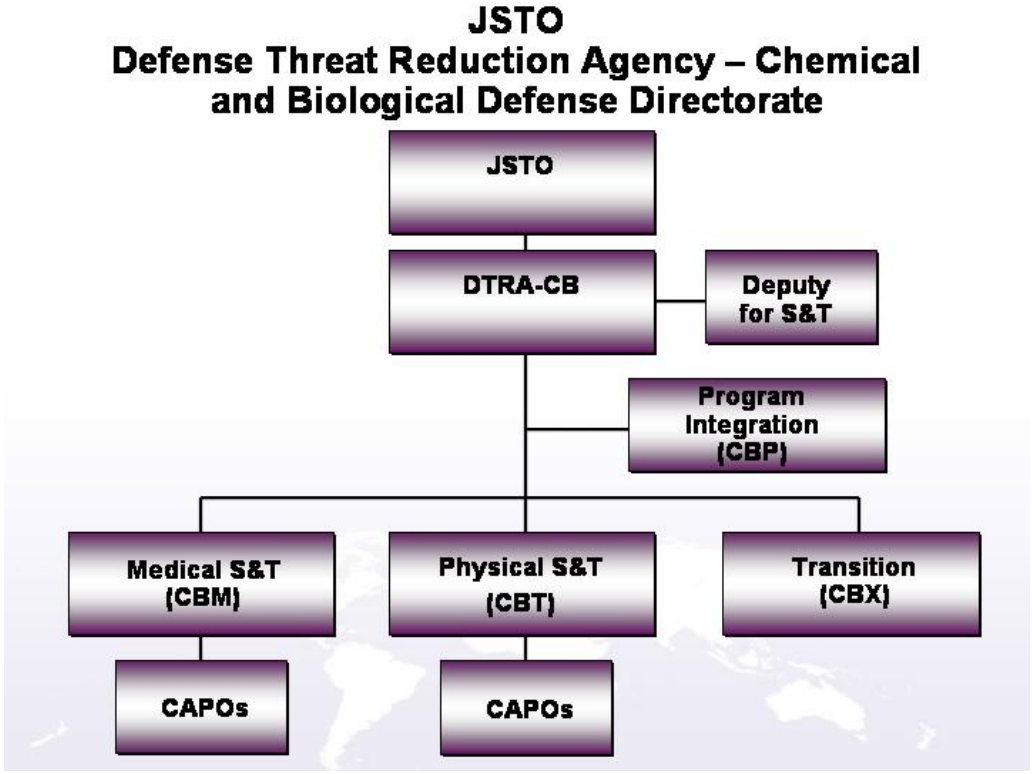


Figure 1. JSTO Organization Chart.

Projects are executed under the CAPO within the appropriate S&T Division of the JSTO. Within the JSTO, the Defense Threat Reduction Agency Chemical Biological Transition Directorate (DTRA-CBX) is tasked with managing and facilitating the transition process. The focus of DTRA-CBX is to assess and transition mature Chemical and Biological (CB) technologies to support future acquisition and current product improvement. The JSTO seeks to provide appropriately mature technologies, which can be inserted into JPEO-CBD acquisition programs. Within the JPEO-CBD, the Science, Technology, and Analysis Directorate is responsible for coordinating and facilitating technology transition. For purposes of this document, DTRA-CBX will be referred to as JSTO and the JPEO-CBD Science, Technology, and Analysis Directorate will be referred to as JPEO-CBD hereafter.

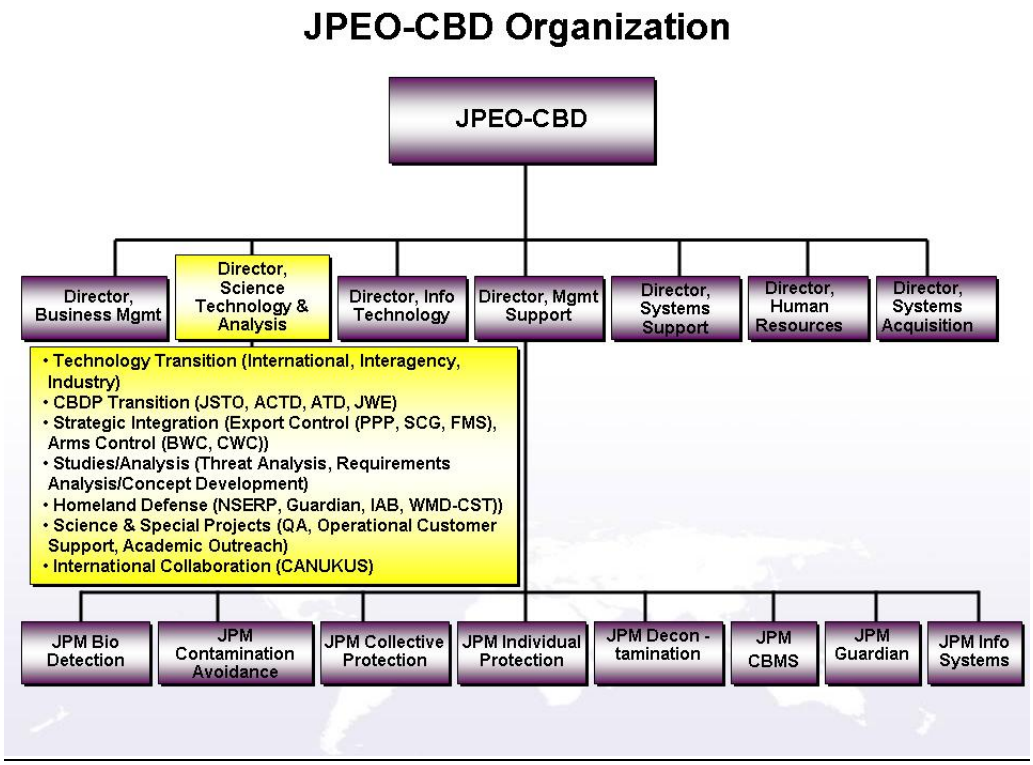


Figure 2. JPEO-CBD Organization Chart.

The following paragraphs outlining technology transition responsibilities are derived from the CBDP Implementation Plan.

JOINT REQUIREMENTS OFFICE FOR CBRN DEFENSE

The responsibilities of the JRO-CBRND pertaining to technology transition are as follows:

1) Serve as the principal Joint Staff representative for CBDP issues and focal point for coordination with the Services.

2) Develop/maintain the Chemical, Biological, Radiological, and Nuclear (CBRN) Defense Joint Overarching Operational Concept and Architecture. Integrate relevant portions of other Joint Operational Architectures.

3) Represent the Services and Combatant Commanders in the DoD Joint Capability Integration and Development System (JCIDS) and act as the Joint advocate for coordinating and integrating Services and Combatant Commander

approved CBRN defense operational capabilities, to include Homeland Defense and Civil Support requirements. Coordinate and manage the CBRN defense requirements document approval process to include approving Service and Combatant Command validated joint requirements documents along with Service/Combatant Command specific approved annexes, as per the latest version of the Chairman, Joint Chiefs of Staff Instruction (CJCSI) 3170.01 and the Joint Requirements Oversight Council (JROC) Memorandum 163-02 dated 9 September 2002.

4) Coordinate with the Services, JPEO-CBD, JSTO, DARPA and the Joint T&E Executive for the CBDP and the Office of the Director for Operational Test and Evaluation (DOT&E) to ensure joint medical and non-medical CBRN defense materiel requirements are effectively evaluated in developmental test and evaluation (DT&E) and operational test and evaluation (OT&E) in accordance with applicable directives, including Food and Drug Administration (FDA) directives for FDA-regulated materiel.

5) Lead the development of the DoD CBDP Program Objectives Memorandum (POM) with JPEO-CBD and JSTO S&T support

JOINT SCIENCE AND TECHNOLOGY OFFICE FOR CHEMICAL AND BIOLOGICAL DEFENSE (JSTO)

The responsibilities of the JSTO pertaining to technology transition are as follows:

1) Manage and integrate chemical and biological science and technology (CB S&T) programs.

2) Generate the supporting Receiver Operating Characteristic (ROC) curves and equipment attributes for the spider chart used in the TRA.

3) Develop and execute CB S&T programs approved by Assistant to the Secretary of Defense for Nuclear, Chemical and Biological Defense (ATSD (NBC)) in response to Joint and Service needs and capabilities requirements.

4) Coordinate closely with JPMs to develop the 6.2 and 6.3 S&T programs (see Appendix I for definitions of the Research, Development, Test and Evaluation (RDT&E) budget activities) to ensure S&T meets acquisition program needs. Ensure effective transition between CB S&T programs and JPEO-CBD acquisition programs by conducting TRAs and TREs. Jointly develop CB S&T strategy roadmaps and CB S&T Research, Development and Acquisition (RDA)

plans.

5) Integrate with Joint Chiefs of Staff (JCS)/JRO-CBRND for CB S&T requirements.

6) Chair the TQR in cooperation with the JPEO-CBD, JRO-CBRND, and the Joint T&E Executive to effectively manage the S&T transition process.

JOINT PROGRAM EXECUTIVE OFFICE FOR CHEMICAL AND BIOLOGICAL DEFENSE (JPEO-CBD)

The responsibilities of the JPEO-CBD pertaining to technology transition are as follows:

1) Provide centralized program management and Joint Service CBDP acquisition program integration for all assigned Joint CBDP non-medical and medical efforts to include planning guidance, direction, control, and support necessary to ensure systems are developed in accordance with DoD acquisition guidance.

2) Establish Technology Readiness Levels (TRL) in conjunction with JSTO and participate in the JSTO chaired TQR with JRO-CBRND and the Joint T&E Executive to identify opportunities for transition of CB S&T technologies to acquisition.

3) Establish exit criteria that must be met in order for the program to transition.

4) Determine the metrics and attributes of the CB equipment to be used in the development of the ROC curve and spider chart.

5) Ensure interagency cooperation and timely transition of technologies to future development programs in order to reduce development cycle times.

6) Provide technical and functional integration across assigned medical and physical science (non-medical) programs.

7) Ensure integration with related DoD materiel programs required for force health protection.

8) Coordinate with JRO-CBRND, the JSTO, and the Joint T&E Executive regarding conduct of a semi-annual JPEO-CBD JPM/JSTO CAPO alignment meeting. Assess S&T program status and ensure S&T programs are synchronized and funded for continued development and transition.

9) Coordinate with JSTO to jointly develop CB S&T Strategy Roadmaps, an RDA Plan, and to conduct TRAs and TREs.

JOINT TEST AND EVALUATION (T&E) EXECUTIVE

The responsibilities of the Joint T&E Executive pertaining to technology transition are as follows:

1) Establish, in consultation with the other Services' T&E Executives, a common set of processes and standards for the conduct of CBDP T&E

2) Identify, in coordination with JPEO-CBD and JSTO, CBDP infrastructure capability and methodology gaps, requirements, and strategies for T&E that are associated with efforts focused on transition to the JPEO-CBD.

3) Establish, review, and supervise CBDP T&E procedures.

4) Oversee CBDP T&E associated with RDA in addition to combat and training development programs.

5) Coordinate on the content and adequacy of the Test and Evaluation Strategy (TES) supporting the TTAs.

Technology Transition Process

The primary intent of this handbook is to focus on transition of CBDP technologies to advanced development acquisition activities (Research, Development, Test, and Evaluation (RDT&E) Activity 6.4). This handbook does not describe the entire acquisition life cycle process. Elements of the overall process will be discussed to provide perspective and points of reference. This handbook assumes that, as a minimum, a valid Initial Capabilities Document (ICD) exists for new technologies currently in development or that a Mission Needs Statement (MNS) and a Joint Operational Requirements Document (JORD) exists for legacy S&T programs.

The DoD preference is to provide capability to the warfighter through evolutionary acquisition. When a program uses an evolutionary acquisition strategy, each increment of capability has a specific set of parameters with thresholds and objectives appropriate to the increment.

In an evolutionary approach, the CBDP acquisition strategy describes the initial increment of capability (i.e., the initial deployment capability), and how it will be funded, developed, tested, produced, and supported. The CBDP acquisition strategy supported by this transition process incorporates similar planning for subsequent increments and identifies the approach to integrate and/or retrofit earlier increments with later increments.

If the capability documents do not allocate increments of capability (leading to full capability) to specific program increments consistent with an evolutionary approach, the JPM and CAPO should work closely with the JRO-CBRND and the user/sponsor (warfighter) to determine whether an evolutionary acquisition approach will serve the user/sponsor needs. Where necessary and acceptable to the user/sponsor, the capability documents should be modified by the JRO-CBRND to include an evolutionary acquisition approach. The technology transition process described here addresses the flexibility of the CBDP process to meet this approach.

The ICD and the Technology Development Strategy (TDS) guide this effort. The TDS will form the basis of the acquisition strategy prepared for the Milestone (MS) B/ technology insertion opportunity. During the development of the TDS, a TES is developed through the efforts of the material developer (JPEO-CBD), the requirements office (JRO-CBRND), and the science and technology provider

(JSTO) and coordinated with the Joint T&E Executive. These processes are described later in the Handbook.

Multiple TRAs may be necessary, but are not required, before the user and developer agree that a proposed technology solution is affordable, militarily useful and based on mature technology. The TDS shall be reviewed and updated upon completion of each technology spiral and developmental increment. Updates shall be approved by the JSTO and JPEO-CBD to support follow-on increments.

The initial capability in an evolutionary strategy represents only partial fulfillment of the overall capability described in the ICD; successive technology transition efforts continue until all capabilities have been satisfied or until no technology can be identified to meet a capability need. In an evolutionary acquisition, the identification and development of the technologies necessary for follow-on increments continues in parallel with the acquisition of preceding increments, allowing the mature technologies to more rapidly proceed into System Development and Demonstration (SDD). Each increment of an evolutionary acquisition program shall have an associated Milestone Decision Authority (MDA) approved TDS. The TDS is the responsibility of the JPM and is required prior to MS A.

The goal of the DoD S&T community is to develop technology as quickly as possible and then successfully transition it to an acquisition program of record. This S&T structure must be flexible and agile in order to respond to diverse and complex challenges. S&T should provide for a competitive pipeline that forces competition and gets technology transitioned.

During Technology Development, the JRO-CBRND prepares the Capability Development Document (CDD) to support program initiation, refines the integrated architecture and clarifies how the program will lead to a joint warfighting capability. The CDD builds on the ICD and provides the detailed operational performance parameters necessary to design the proposed system. A MS B decision follows the completion of Technology Development.

CBDP S&T projects intended for a MS B program initiation, S&T projects funded in RDT&E Advanced Technology Development (Budget activity 6.3), and S&T projects identified for programs in Applied Research (Budget Activity 6.2) require a TDS and a TES. These efforts now require a TTA. Next, a TRE Plan is developed in order to ensure that the technology will meet JPM requirements and is ready to transition as well as to ensure test capabilities and methodologies exist to adequately evaluate the technology. TRLs, ROC curves, and metrics are then established. If necessary, a TRE is conducted to gather data to support the next step in the process, the TRA. If the TRA concludes that the technology has met the criteria outlined in the TTA, the technology may successfully transition to the acquisition activity. Figure 3 outlines how the technology transition process and

documentation timeline coordinates with the acquisition and capabilities development processes.

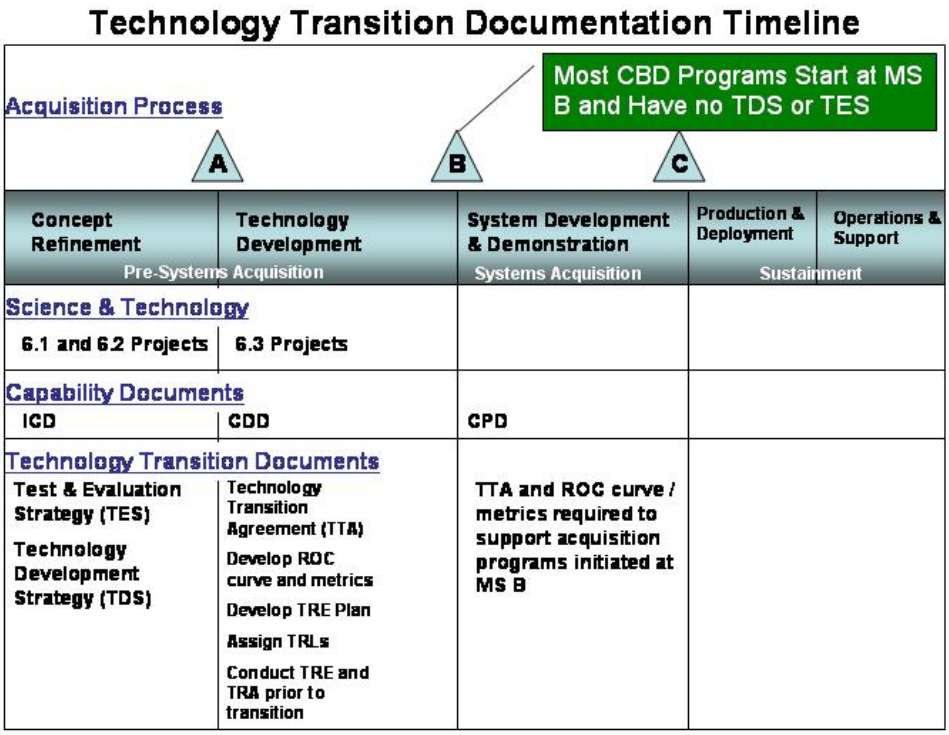


Figure 3. CBDP Technology Transition Process/Documentation Timeline.

The CBDP will coordinate with other Departments and agencies along with academia, industry, and international partners (Figure 4) to identify promising technologies that can be incorporated into existing or new programs to fill JRO-CBRND identified capability gaps. These technologies may evolve from DARPA,

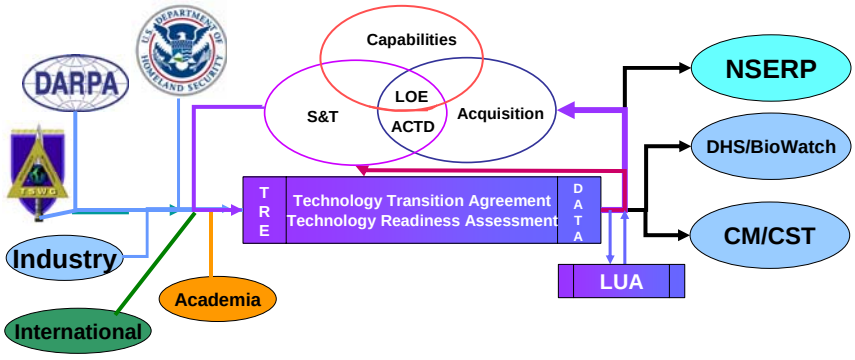


Figure 4. Overview of the CBDP Technology Transition Process.

the Technical Support Working Group (TSWG), laboratories, research centers, academia, or foreign and domestic commercial sources. The CBDP transition

process will reduce the risks of introducing these technologies into the acquisition process; and promote coordination, cooperation, and mutual understanding of technology issues. In some cases, an increment of capability may be demonstrated during a TRA in which case a Limited Utility Assessment (LUA) may be conducted to further reduce transition time to the program of record. The conduct of S&T activities shall not preclude, and where practicable, shall facilitate future competition to provide capabilities to the CBDP acquisition process.

Management Tools for Technology Transition

In the past, many S&T programs concluded but technologies did not transition because: 1) the acquisition program was not ready to receive the technology, 2) there was no funding to support the transition, or 3) there was no acquisition program requirement to support the transition.

The management tools and process outlined in this handbook assures mature technologies transition to acquisition programs, close coordination between JSTO, JPEO-CBD, JRO-CBRND, and the T&E Executive occurs in a timely manner. Additionally adequate funding is programmed for technology transition, T&E capability, and T&E methodology development and planning. Capability documents, beginning with the Initial Capabilities Document (ICD), must clearly articulate the capability and the need for the technology. Coordination is essential to ensure that the JSTO S&T programs, critical to the execution of a program of record, are aligned. Figure 5 depicts the CBDP Alignment Process.

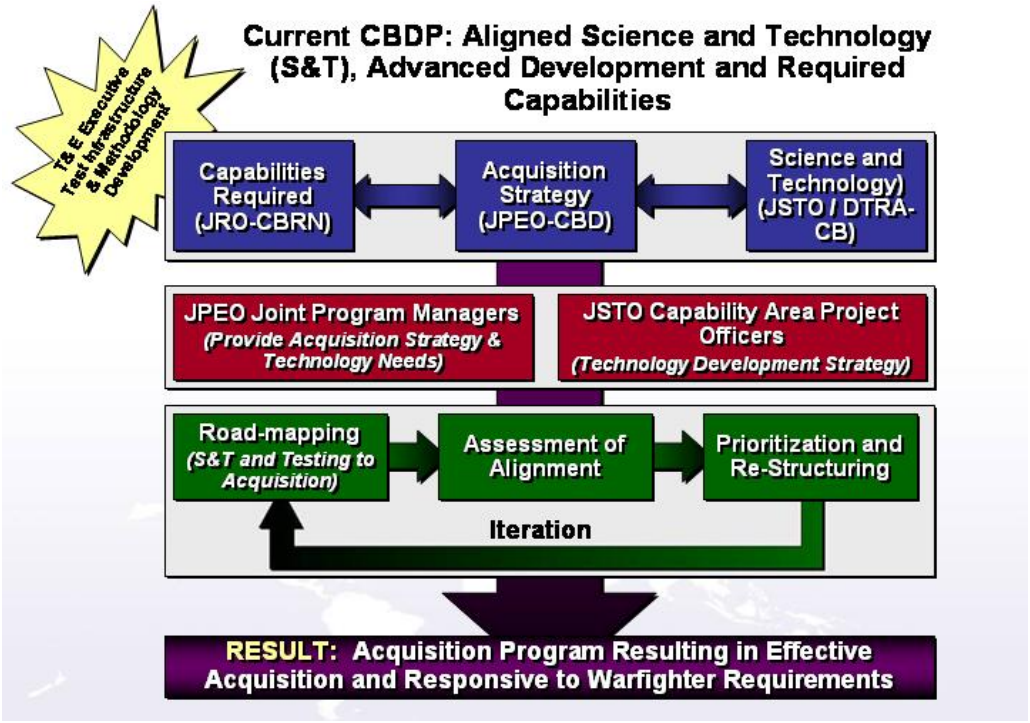


Figure 5. CBDP Alignment Process.

The primary tools used to facilitate the CBDP technology transition process are:

- Technology Development Strategy (TDS);
- Test and Evaluation Strategy (TES);
- Technology Readiness Level (TRL);
- Manufacturing Readiness Level (MRL);
- Technology Transition Agreement (TTA);
- Technical Readiness Evaluation (TRE);
- Technology Readiness Assessment (TRA);
- Receiver Operating Characteristic (ROC) Curve; and
- Transition Quarterly Review (TQR).

Figure 6 outlines the CBDP technology transition products, responsible organizations and required timelines.

CBDP Technology Transition Responsibility Matrix		
Documentation/Process	**Responsible Organization**	**When Required**
TDS	JPM	Pre-MS A
TES	JPM	Pre-MS A
TRL definition specific to program	JPM	Pre-TRA; 90 days prior to MS B or transition
MRL	JPM	Pre-TRA; 90 days prior to MS B or transition
TTA	JSTO	MS A
ROC Curve/Spider Chart Metrics and Attributes	JPM	MS A; update as needed
Data to develop ROC Curves & Spider Charts	JSTO	MS A; update as needed
TRE	JSTO	Pre-MS B/transition as needed
TRE Plan	JSTO	1 year prior to TRE
TRA	JSTO	Pre-MS B/transition or as needed
TQR Assessment Charts	JSTO	Quarterly
CBDP POM Alignment Charts	JPM	Annually, or as needed
CB S&T Strategy Roadmaps	JSTO	Annually, or as needed
RDA Plan Roadmaps	JSTO	Annually

Figure 6. CBDP Technology Transition Responsibility Matrix.

TECHNOLOGY DEVELOPMENT STRATEGY

The TDS provides rationale for adopting either an evolutionary acquisition strategy or a single-step-to-full-capability strategy. For an evolutionary acquisition, either spiral or incremental, the TDS will include a description of the capability/ system in which the technology is integrated and a preliminary description of how the program will be divided into technology spirals or developmental increments. The TDS outlines a program strategy, incorporating overall cost, schedule, and performance goals for the total research and development program. Also included are exit criteria for demonstration in a relevant environment, for the first affordable increment of technology. Further, the TDS contains a description of tests required to ensure that the goals and exit criteria for the first technology spiral demonstration are met.

The acquisition framework incorporates a Technology Development Phase focused on the development, maturation, and evaluation of the technologies needed for the capability under consideration. Phase activities concentrate on maturing those technologies (consistent with recommended TRLs) and demonstrating readiness to proceed with program initiation. The Technology Development Phase ends when the MDA determines that technologies are sufficiently mature. This determination, along with the satisfaction of other statutory and regulatory requirements, supports program initiation. The TDS is a statutory requirement (Sec 803, Pub.L, 107-314) documented in the Defense Acquisition Guidebook (DAG) which focuses specifically on the activities of the Technology Development Phase. Where feasible, the TDS should also discuss activities associated with the post-program-initiation phases of the planned acquisition.

The TDS precedes the formal Acquisition Strategy and is required for MS A. The TDS is updated at subsequent milestones and subsumed into the Acquisition Strategy. If the Acquisition Strategy is approved at MS A, the TDS may be included in the Acquisition Strategy. While there is no mandatory format for the TDS, Public Law 107-314, Section 803, requires the following minimum content:

- A discussion of the planned acquisition approach, including a summary of the considerations and rationale supporting the chosen approach. For the preferred, evolutionary acquisition approach, whether spiral or incremental, DoD Instruction 5000.2 requires the following details:
- A preliminary description of how the program will be divided into technology spirals and development increments;
- The limitation on the number of prototype units that may be produced and deployed during technology development;

- How prototype units will be supported; and
- Specific performance goals and exit criteria that must be met before exceeding the number of prototypes that may be produced under the research and development program.
- A discussion of the planned strategy to manage research and development. This discussion must include and briefly describe the overall cost, schedule, and performance goals for the total research and development program. To the extent practicable, the total research and development program should include all planned technology spirals or increments.
- A complete description of the first technology demonstration or TRE. The description must contain specific cost, schedule, and performance goals, including exit criteria, for the first technology spiral demonstration.

DoD Instruction 5000.2 requires that each increment of an evolutionary acquisition program have a MDA-approved TDS. The Instruction also requires that the TDS be reviewed and updated upon completion of each technology spiral and development increment and that approved updates support follow-on increments

TEST AND EVALUATION STRATEGY

The TES is an early T&E planning document that describes the T&E activities starting with Technology Development and continuing through SDD into Production and Deployment. Over time, the scope of the TES will expand and evolve into the Test and Evaluation Master Plan (TEMP) due at MS B. The development of the TES is the responsibility of the projected program of record material developer supported by the JSTO CAPO. The TES is coordinated with the Joint T&E Executive. The TES is part of the TTA and is reviewed as part of the TQR process.

The TES describes, in as much detail as possible, the risk reduction efforts across the range of activities (e.g., Modeling & Simulation (M&S), DT&E and OT&E, etc.) that will ultimately produce a valid evaluation of operational effectiveness, suitability, and survivability before full-rate production and deployment. The TES is a living document and should be updated as determined by the T&E Working-group Integrated Process Team (WIPT) during the Technology Development Phase. The development of the TES will require early involvement of testers, evaluators, and others as a program conducts pre-system acquisition activities. These personnel will provide the necessary expertise to ensure nothing is overlooked in laying out a complete strategy. The TES should be consistent with and complementary to the Systems Engineering Plan (SEP).

The TES describes the system in which the technology is to be integrated, the process for technology integration, and how the component technologies being

developed will be demonstrated in a relevant environment to support the program's transition into the SDD Phase. The TES addresses the concept of employment and operational strategy supporting a possible early operational assessment of the technology. The TES contains hardware and software maturity success criteria used to assess key technology maturity for entry into SDD. The TES is the planning document used to begin developing the entire program's T&E Strategy, and includes the initial T&E concepts for Technology Development, SDD, and beyond.

For programs following an evolutionary acquisition strategy with more than one developmental increment, the TES should describe how T&E and M&S would be applied to confirm that each increment provides its required operational effectiveness, suitability, and survivability as would be required of a program containing only one increment. The development of the TES establishes an early consensus among T&E WIPT member organizations on the scope of how the technology or system will be tested and evaluated, with particular consideration given to needed resources, in order to support Planning, Programming, Budgeting, and Execution (PPBE) process activities. The TES applies to S&T efforts associated with development of subsystems, components, and technologies supporting program acquisition strategies.

There is no prescribed format for the TES, but it should include the following items, to the extent they are known:

- Introduction and objectives of the system-specific technical and operational evaluations that will support future decision events;
- System description, mission, concept of operations, and major performance capabilities from the ICD. Identify new technology and the plan to identify associated risk;
- Acquisition strategy concept - For programs following the preferred evolutionary acquisition strategy, the TES should describe how T&E and M&S would be applied to each increment. It should show how each increment would ultimately provide a demonstrated level of operational effectiveness, suitability, and survivability, and meet user needs with a measurable increase in mission capability;
- Time-phased threats to mission accomplishment;
- Anticipated concept of operations, including supportability concept;
- Technical risk reduction testing, including any new or critical technologies identified in the TDS;
- Anticipated component and sub-system developmental testing that begins after MS A;
- T&E strategy for SDD;
- Critical operational and live fire (if appropriate) issues;
- Scope and structure of the operational and live fire evaluations;
- Likely sources of required data;

- Major T&E design considerations;
- Hardware and software maturity success criteria;
- T&E schedule;
- Anticipated M&S used for future system evaluations; and
- T&E funding estimates in enough detail to permit programming and budgeting.

For all programs which the Office of the Secretary of Defense (OSD) T&E maintains oversight, the program manager or leader of the concept development team, with the T&E WIPT providing support, must submit the DoD Component-approved TES to OSD for staffing and approval before MS A. Early involvement of testers and evaluators will ensure a better product and will expedite the approval process, as issues will be addressed and resolved early through the Integrated Product and Process Development (IPPD) process.

The TES should be submitted 45 days prior to MS A so that an OSD-approved document is available to support the decision. The TES portion of the TTA for S&T projects supporting programs on the OSD T&E Oversight List is approved through the Joint T&E Executive. For programs not on the OSD T&E Oversight List, the JPEO-CBD, or designated representative, approves the TES.

TECHNOLOGY TRANSITION AGREEMENT

The revision of the Federal Acquisition Regulation (FAR) DoD 5000 brought about significant changes in the way technology transitions from the technical developer to the advanced developer (i.e. the JPM). An integral part of this process is the use of the TTA as taught by the Defense Acquisition University (DAU). The DAU S&T Manager's course (STM 301 and 302) advocates the use of TTAs to document the commitment of the requirements/resource sponsor (in the case of the CBDP, this is the JRO-CBRND), S&T activity (JSTO), and acquisition program sponsor (JPM) to develop, deliver, and integrate a technology/product into an acquisition program.

The TTA process can be articulated from the "Technology Pull" or "Technology Push scenario" (see figure 7). In the case of "Technology Pull", the JPM conveys the technology need to the JSTO and then closely coordinates with the JSTO to "build" an S&T program to meet that capability and develop the TTA to support the technology development, TES, and transition. In the "Technology Push" scenario, the JSTO may have a proposal for a technology that may not satisfy a current requirement but may provide substantial benefit to the program justifying an unplanned product improvement or horizontal technology insertion into an existing program of record. The JSTO would then coordinate with the JPM to jointly develop and finalize the proposal and subsequent TTA. Close coordination

between the CAPO and JPM ensure that the TTA is developed for the technology that will most likely meet the needs of the warfighter.

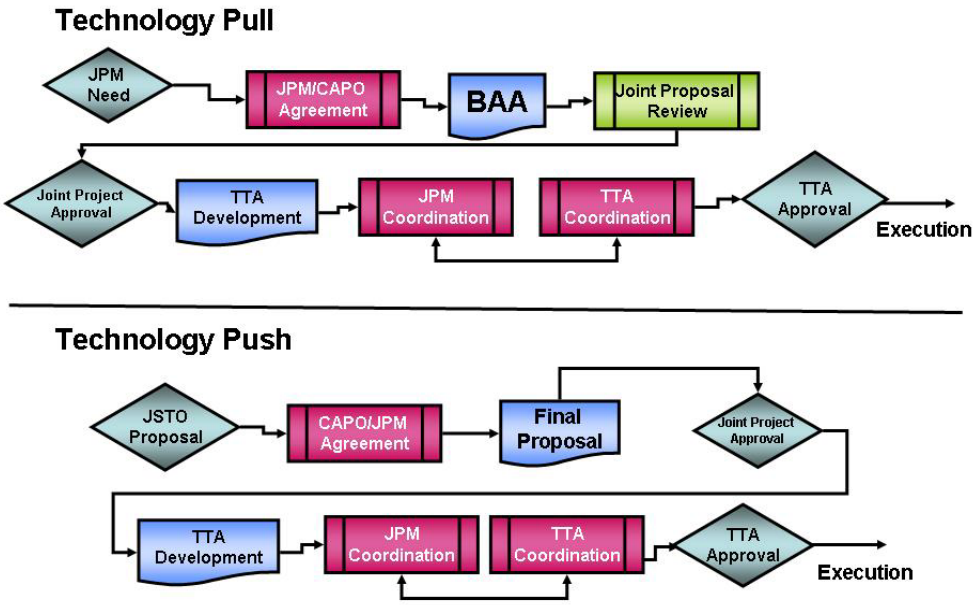


Figure 7. CBDP Technology Pull and Technology Push.

The TTA is a Memorandum of Agreement (MOA) between the JSTO (technology developer) and the JPM (intended receiver of a technology or capability development). The TTA is the primary vehicle for the transition process of transitioning 6.3 technologies, and in special cases 6.2 technologies or technical information, from the JSTO scientific developer to the appropriate JPM. A TTA documents the program exit criteria of the JSTO to develop, deliver, test, and evaluate a technology/product for an acquisition program. The TTA provides a clear assignment of responsibilities of what each party provides in order for transition to occur. A TTA is developed for each JSTO S&T project in which the next phase is to be executed is by the acquisition activity (JPM). For the CBDP, TTAs are applicable to all JSTO Physical Science and Medical 6.3 programs and some 6.2 programs with identified technologies or technical information products but do not apply at the project level. To clarify, several 6.2 projects may be conducted concurrently leading to a single technology that will transition through a 6.3 effort. For example, a project for a collector, a sensor, and a method of data processing would culminate in a 6.3 prototype for a biological agent detection system. The TTA identifies the "target" 6.4 program of record to which the 6.2 or 6.3 technologies are intended to transition. TTAs are required for all 6.3 CBDP programs, with a few exceptions. One possible exception is a 6.3 program established for tests that complement the development of a particular technology but is not by itself solely for that technology (i.e. a 6.3 project to validate environmental test methodologies that are applicable to various detection systems under development). Funding for 6.3 programs with potential technologies

lacking TTAs may be withheld, by the Director, JSTO, until a valid TTA is provided. For programs initiated post MS A, the TTA performs the function of the TDS and TES.

There are two key factors in the development of the TTA: 1) exit criteria that must be met for the program to transition and 2) a determination of the metrics and attributes of the CB equipment to be used in the development of the ROC curve and spider chart within development processes. The JPM establishes the technology exit criteria so that advanced planning for test methodology development, testing, evaluation, and facilities construction can be programmed. The JPM establishes the metrics and attributes necessary for the generation of ROC curves and spider charts. The JSTO is responsible for the generation of the data supporting ROC curves and sensor attributes for the spider chart used in the technology assessment. A template for a TTA can be found in Appendix H. The TTA development process is depicted in figure 8.

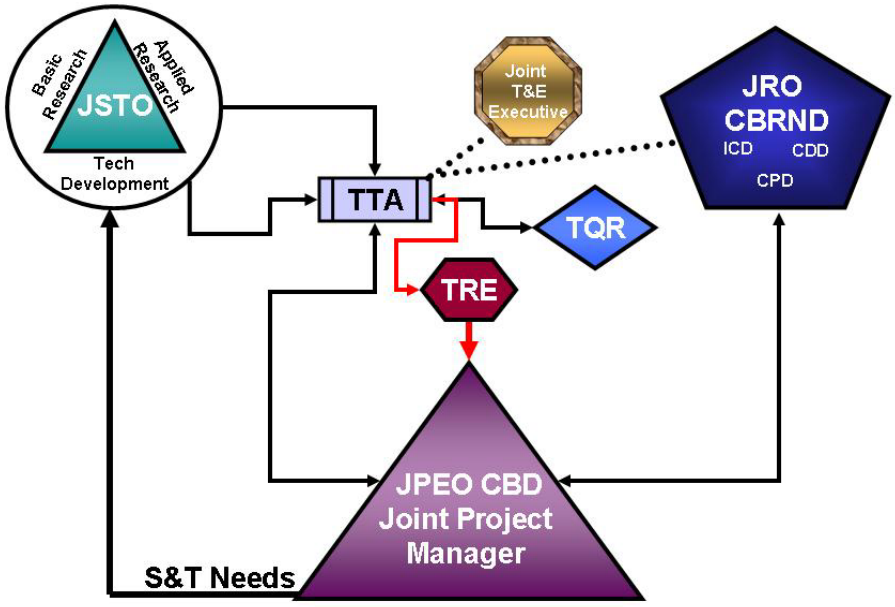


Figure 8. CBDP Technology Transition Agreement Process.

TTA Termination: Once signed, a TTA will be terminated only if: 1) the requirement in a JRO-CBRND source document is superseded or deleted, 2) the requirement for that technology/capability no longer exists, 3) the requirement for the technology has already been met, or 4) no technology can be identified within the necessary timeline for incremental acquisition. Funding constraints, developmental delays, immaturity of technology as demonstrated through TRA, or initial failure to meet exit criteria under T&E will not be used as rationale to terminate a TTA. However, the intention is not to "perpetuate" R&D.

Transition Exit Criteria: All technology to be transitioned from the JSTO to the JPM will have exit criteria established to which the technology is tested and

evaluated and is documented in a TTA. For effective and timely transition, exit criteria will be determined upon entry to MS A. Exit criteria will be obtained and developed from paragraph two (2), Required Capability and paragraph three (3), Concept of Operations Summary, of the ICD. Exit criteria attributes should be measurable and quantifiable to ascertain if the technology meets program requirements. In the event that exit criteria is not specified or well defined in the ICD, the JSTO and the JPM will develop exit criteria to evaluate that the technology meets program requirements prior to transition. With very few exceptions (i.e. to satisfy an Urgent Needs Statement (UNS) or Operational Need Statement (ONS)), all technology to be transitioned to the JPM will be evaluated to ensure it meets the program criteria.

The process involved in the identification, development, and intra/interagency staffing coordination of TTAs is as follows:

TTA Coordination: The TTA is developed and coordinated for approval by an assistance team from DTRA-CBX and the JPEO-CBD Science, Technology, and Analysis Directorate. Both organizations are responsible for transition within the CBDP. The TTA assistance team supports both the CAPOs and JPMs in the construct of each TTA as an adjunct element of the respective acquisition activity and S&T program. The TTA assistance team must be familiar and experienced in the respective capability areas they support.

The JSTO (via DTRA-CBX) coordinates, as part of a transition team supporting DTRA-CBT (Physical S&T Division Chief) and DTRA-CBM (Medical S&T Division Chief), a list of S&T projects that have been identified as potentially having a "product, software, or information" for transition that will require a TTA. DTRA-CBT and DTRA-CBM Division Chiefs and the supported JPM review and validate the lists of S&T projects that require TTAs. The TTA Assistance Team coordinates between the CAPO and JPM to develop a TTA in accordance with this handbook and serve as subject matter experts for TTA development supporting the CAPO/ JPM.

Although transition of 6.2 projects to a 6.4-level of advanced development is uncommon, it is possible; all 6.2 projects will be reviewed to determine if transition potential exists. TTAs will be developed for 6.2 projects, applied research, in all cases where the focus of the applied research effort is to resolve a capability gap.

Prior to signature, the draft TTA is provided for coordination and concurrence to the following: the JPEO-CBD (JPEO-CBD Director of Technology and Product Director for T&E Systems Support (PD-TESS)), JPM, DTRA-CBX, DTRA-CBT and DTRA-CBM Division Chiefs, JRO-CBRND and the Joint T&E Executive. This coordination process serves to review, edit and finalize the TTA to the point where it is ready for signature.

The TTA is signed by the performing CAPO and the JPM of the Program of Record (POR) targeted for transition.

After signature, the TTA is periodically reviewed for currency as a part of the TQR process.

TECHNOLOGY READINESS EVALUATION PLAN

The TRE Plan is developed by JSTO in close coordination with JPM and the Joint T&E Executive. The TRE Plan documents the strategy for evaluating the T&E capability development necessary to test and evaluate both S&T and commercial products that may be considered for transition to a joint program. The TRE Plan should be prepared in draft form no later than one year prior to the scheduled TRE and should be coordinated among all concerned parties. The final draft should be prepared and coordinated no later than one month prior to completion of the development effort. The TRE Plan will be part of the MS B (or MS A process in the case of medical products) approval process and will be reviewed for sufficiency, quality, and adequacy. The TRE Plan will, at a minimum, include and describe the following areas in detail:

- Program description
- Projected transition date
- Key Performance Parameters, thresholds and objectives
- Projected specific capability dates
- Current status of the program to include fiscal year funding levels
- Risk analysis and mitigation plan
- Timeline with milestones and key events
- TRLs and MRLs
- Integration strategy of product into the JPM Acquisition program (alignment)

Technology Transition Assessment Tools and Processes

TECHNOLOGY READINESS LEVELS

TRLs are measures of technical maturity and form the basis of the technology assessment. The MDA will consider the recommended TRL when assessing program risk. The JPEO-CBD, executed through the appropriate JPM, has the lead responsibility to establish TRLs for technologies, components and systems focused on transition to existing programs of record. The JSTO is responsible for assessing the maturity of those technologies, systems, and components against the TRLs and within the scope of the supporting TTA through the TRA process. In other words, the JSTO recommends the TRL and the JPM assigns the TRL. TRLs will be assigned to all components and subcomponents of the technology being evaluated. The overall TRL for a system is determined by the lowest assigned TRL for the components and subcomponents within the system. A guide to assigning TRLs can be found in Appendix A. TRL definitions are located in Appendix B.

The use of TRLs to manage the integration of emerging technologies into product development efforts has been found to dramatically improve program success rates (General Accounting Office (GAO) report "Best Practices: Better Management of Technology Development Can Improve Weapon System Outcomes" (GAO/NSIAD-99-162). The report identifies three key knowledge points that directly effect product development risks, cycle times, and costs: 1) when a match is made between a customer's requirements and the available technology; 2) when the product's design is determined to be capable of meeting performance requirements and 3) when the product is determined to be producible within cost, schedule, and quality targets (Figure 9). To realize their full benefit, TRL assessments are best performed at the first knowledge point, prior to transition into product development.

Figure 9 can be compared to the defense acquisition framework found in DoD Instruction 5000.2 (Figure 10). Knowledge point 1 is roughly equivalent to MS B in this framework.

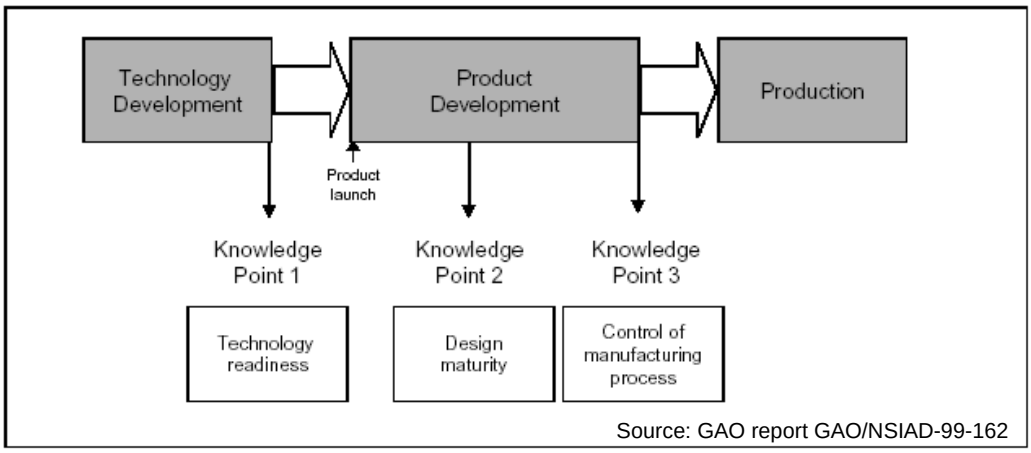


Figure 9. Key Knowledge Points in the Acquisition Process.

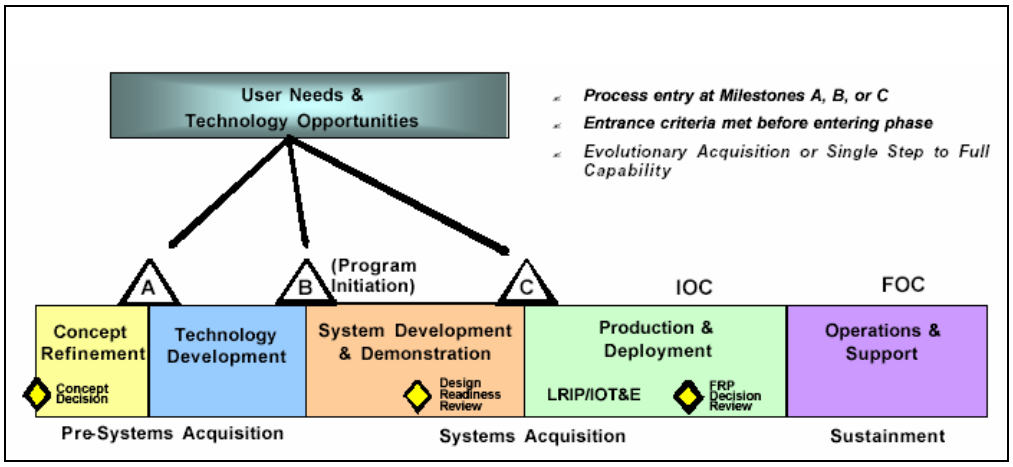


Figure 10. Defense Acquisition Framework.

TRLs for both components and entire systems are validated during TRAs. DoD Instruction 5000.2 establishes a requirement for TRAs for Acquisition Category (ACAT) 1D and ACAT 1AM programs prior to MS B and C.

MANUFACTURING READINESS LEVELS

MRLs are metrics used to assess the ability of the industrial base to mass produce the technology that is to be transitioned to advanced development based on current industrial manufacturing processes and capabilities. As defined by the DoD TRA Deskbook, "MRLs are measures used to assess system

engineering/design process and maturity of a technology's associated manufacturing processes." MRL definitions can be found in Appendix G.

The JPM has the lead responsibility of assigning MRLs. If requested by the JPM, the JSTO CAPO will conduct an MRL assessment. When the JPM elects to conduct an MRL, sufficient time will allotted so as to provide it at least 90 days prior to the transition/MS B review. The TRA panel will use the MRL evaluation criteria to evaluate the maturity of the technology to be transitioned to ensure that it is mature enough to meet the JPM's needs and is manufacturable and affordable in the quantities required to meet fielding goals and timelines.

EQUIPMENT METRICS AND ATTRIBUTES

The performance of CB agent equipment will be characterized by a number of interrelated parameters (e.g., metrics and attributes). These metrics and attributes will be developed by the responsible JPM and reflect the performance characteristics of sensors, protective equipment, decontamination solutions, and models used in the Joint CB Defense Program. For purpose of illustration, sensor equipment will be discussed in this handbook, but the methodology is applicable in all CB defense commodity areas. Metrics such as sensitivity, probability of correct detection, false positive rate, and response time which will be developed in a sensor ROC curve (See Figure 11.). Attributes include factors such as weight, cost, reliability, maintenance, and logistic factors to name only a few. The Spider chart, Figure 12, will be generated to capture the metrics and attributes of a desires CB defense technology. The TTA will specify the metrics and attributes to be used in the development of the technology.

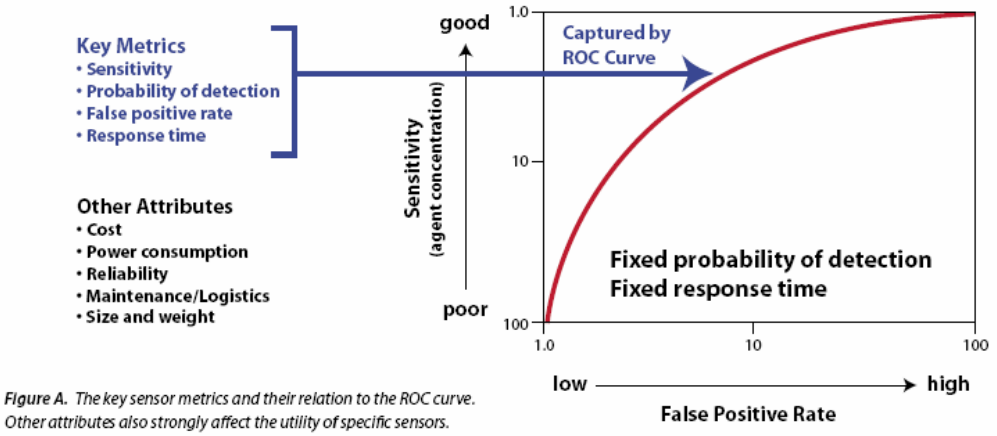


Figure 11. Example of Receiver Operating Characteristic (ROC) Curve for a CB sensor

For example the JPM, and the JSTO CAPO will define the ROC curves for a sensor to include time as the independent variable and have integrated levels of detection overlaid on them (Figure 11).

Sensor metrics will relate sensor sensitivity rate to false positive at a given detection confidence for a determined response time. Therefore, sensor metrics to be developed under each sensor TTA are;

- Sensitivity
- Probability of Detection
- False Positive Rate
- Response Time

In addition to the metrics, sensor attributes will be developed and included in the sensor TTA for development in the 6.3 program. These attributes will be agreed to in the TTA and may include some or all of the following.

Initial cost affects how equipment is employed and the numbers of sensors/equipment employed. Disposable sensors/equipment should be very inexpensive, while non-disposable sensors/equipment deployed with units on the battlefield could cost significantly more. In contrast, a single sensor unit for protecting a facility from external attack may be quite expensive, whereas multiple sensors/equipment employed for internal attacks might cost less. Depending on performance and mission requirements, equipment costs could change dramatically.

Operating cost is comprised of any cost incurred after the initial acquisition expenditure. This includes both logistic and maintenance costs, consumable supplies, repair parts, and operator training. Operating cost can range from very low for disposable sensors/equipment, to lifetime costs that greatly exceed the initial cost of the equipment for more paramount sensors/equipment. If only one sensor/piece of equipment is to be maintained, a higher operating cost may be more tolerable than in a situation where large numbers of sensors/equipment are deployed.

Power consumption is critical to the mission as it effects the mission profile of the equipment and the concepts of employments. For force protection roles, the equipment should typically be battery powered. A disposable sensor/piece of equipment should have a very low power requirement. For building equipment systems, an AC line would be available to provide power. Power consumption must also be considered in light of mission duration.

Maintenance consists of the actions taken to keep materiel in a serviceable condition or restore it to serviceability.

Reliability is the probability that an item will perform to its intended function for a specified interval under stated conditions. The longer the sensor performs without experiencing an unexpected failure (i.e. the mean time between failure (MTBF)), the better the reliability. It is assumed that stated routine maintenance requirements are met.

Ruggedness is the ability to withstand shock, vibration, and exposure to harsh weather conditions and even some effects of enemy nuclear weapons (e.g. electromagnetic pulse (EMP)).

Form factor, i.e., the size, weight, and shape of the equipment, is of particular concern in the battlefield role where sensors/equipment are frequently moved. Man portable, small sensors/equipment are highly desirable in this role. Small form factor is normally less critical from the facility standpoint because sensors/equipment will usually remain in place.

Environmental considerations are the set of guidelines meant to protect the environment, the military, and noncombatant civilian populations. These include issues such as safe disposal of reagents and used consumables to excessive noise and laser eye-safety. These can have a serious impact on equipment acceptance.

The examples here are focused on sensor metrics and attributes; however this approach is also intended to apply across the spectrum of CBDP capability needs. The JPM is responsible for the definition of metrics and attributes of technology to support an acquisition strategy.

These metrics and attributes will be developed for the TTA in order to assist the JPM in transitioning technologies appropriately. Some important facts to remember when developing equipment metrics are listed below:

- Sensitivity will always be stated with the probability of detection, the false positive rate, and the response time.
- Equipment testing used to evaluate equipment performance in the 6.3 process must occur in environments in which the sensor/equipment will operate and must be generated with different levels of detection confidence in a single environment.
- ROC curves must be developed for sensors/equipment at each stage of the development to determine readiness for the next developmental stage.

Equipment metrics and attributes derived from the ROC curves and testing are then graphically represented in spider charts to compare sensors/equipment or to judge the overall equipment performance (See Figure 12). In a spider chart, each of the sensor metrics is assigned a "leg" on the chart, with better performance moving out from the center. The performance of the equipment can then be

plotted. The spider chart is then used as a means of comparison between sensors/equipment, or simply as a means to judge overall efficacy of a given sensor/piece of equipment.

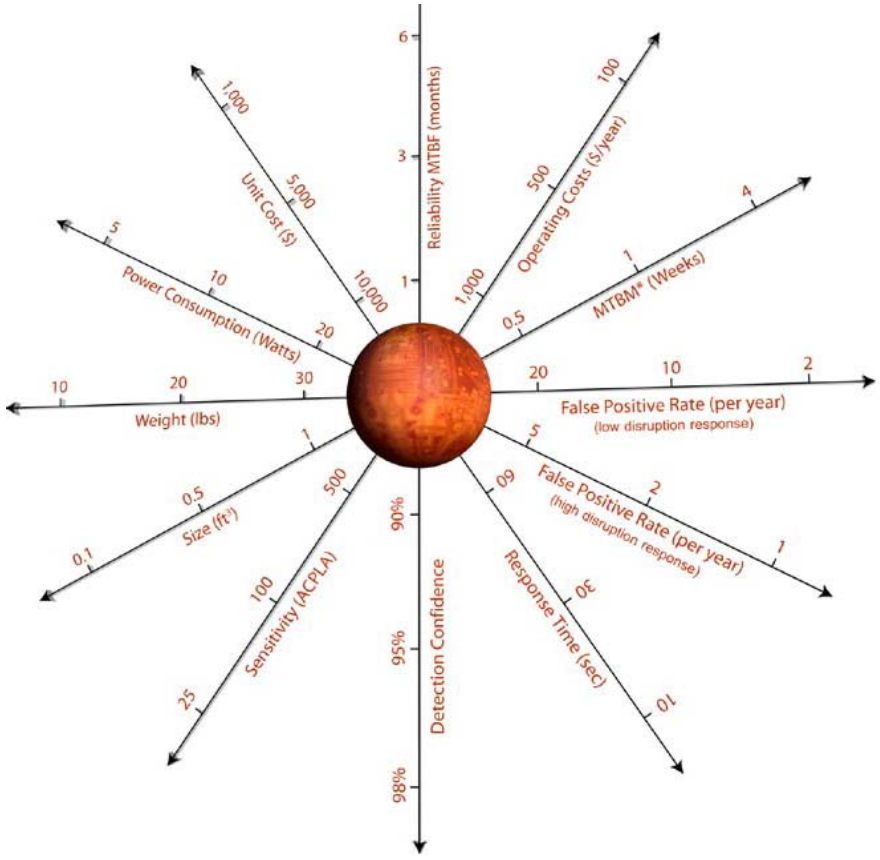


Figure 12. Spider Chart Example.

ROC curves (as applicable) with spider charts will be included in the TTA and used in the TRA process as a tool to determine the TRL of the technology. A copy of the CB Sensor Standards Study can be found on the JPEO-CBD Integrated Digital Environment (IDE) under the Technology Directorate section. The study's findings have been incorporated in this document.

TECHNOLOGY READINESS ASSESSMENT

A TRA is the review, conducted by an independent assessment panel; for a specific component or system that has been determined to have met the criteria in the TTA (see Appendix A for methodology to develop criteria). The TRA Panel

is chaired by the JSTO. Membership on the panel shall include representation by the JPM for whom a technology is being developed in the TTA.

A TRA is conducted before each MS B and MS C event. In the case of medical programs, a TRA may be required prior to MS A, as the majority of medical products transition at MS A. Before a technology attains MS B status and transitions to the SDD stage, a TRA must have been conducted and the technology must have been demonstrated in a relevant environment (or an operational environment, if possible). This will occur approximately sixteen (16) weeks before the designated MS review date. The assessment will be performed at the direction of JSTO and must include all critical technologies identified by the JPM and can include additional technologies that the JSTO CAPO deems critical. Critical technologies are defined as those technologies the program/system depends on to meet capability thresholds. While much of the information comes from the JPM, the actual assessment is made independent of the JPM. Figure 13 describes the basic TRA process.

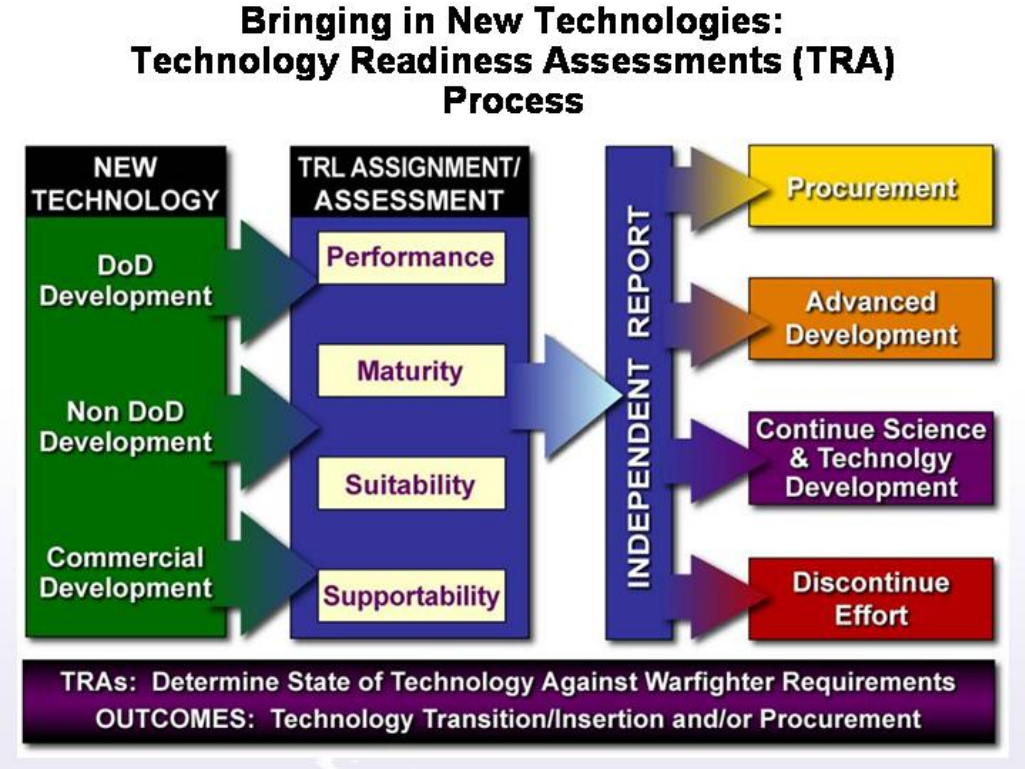


Figure 13. Technology Readiness Assessment Process.

For Hardware systems with incremental development strategies, each successive incremental design improvement will require a TRA to be conducted for that increment before the program receives a MS B or MS C review. The spiral development process is normally used in software development. In the TRA process, software is considered an integral part of the system or subsystem in

which it operates. As such, demonstration of technical maturity at the subsystem or system level must include a demonstration of the associated software.

The TRA Deskbook, published by the Deputy Under Secretary of Defense for Science and Technology (DUSD (S&T)) provides an overview of the TRA process and its relationship to the acquisition process.

TECHNOLOGY READINESS EVALUATION

TREs are paper studies and/or field and laboratory tests used to gather data in support of a TRA on specific technologies to meet JPM program requirements. TREs are managed by the JSTO DTRA-CBX division. DTRA-CBX works closely with both the JPM and the JSTO CAPO to ensure that the TRE will meet the JPM's needs. TREs are conducted on S&T technologies prior to transition to an acquisition program to support a MS decision or pre-planned product improvement (P^3I). Ideally, the TRE should be accomplished at the beginning of the Concept Refinement phase to determine what technology already exists that may possibly satisfy the acquisition program requirements. Data collected during a TRE is used to determine the effectiveness and suitability of a technology to meet program criteria set forth by the JPM. JPMs are therefore prepared to transition a technology, component or system which is supported by a TRA/TRE and with a good understanding of the technical risks derived from the maturity level resolved through the TRL.

TRANSITION QUARTERLY REVIEW (TQR)

The TQR is a high level execution review of the efforts necessary to transition a technology to the appropriate JPM. The TQR is conducted with membership of the JPEO-CBD, JSTO, JRO-CBRND and the Joint T&E Executive.

The purpose of the TQR is to make recommendations to the appropriate management/execution entity to insure confidence in the transition of acceptable, mature capability on time to the material developer.

The authority for conducting the review is derived from the USD Memorandum: Implementation Plan for the Management of Chemical Biological Defense Program, dated 22 Apr 2003. The memorandum directs the TQR team to:

- Identify candidate S&T technology areas/programs for future transition and plan for current transition.

- Review transition-testing programs and plans for tests and test methodology development.
- Report on transition tests conducted and the results.
- Develop future year program transition requirements.
- Review status and currency of TTAs.
- Review and update CBDP alignment charts.

Medical Transition Process

Medical S&T falls into two categories: 1) drugs (encompassing, pre-treatments, vaccines and therapeutics) and 2) diagnostics (which include detection and identification from clinical material). A fundamental difference between medical acquisition programs and other DoD acquisition programs is the decision to pursue the development program while the effort is still in the technology base, well in advance of the traditional MS B transition point for DoD programs. The Food and Drug Administration (FDA) regulatory process requires product and manufacturing process definition to be well defined prior to human clinical trials. Changes in a product, once clinical trials have begun, may negate previously accomplished trials resulting in increased cost and schedule slip due to having to repeat clinical trials. Medical product development and production programs must therefore be defined early. The medical program utilizes the DoD system acquisition process defined in the DoD 5000 series documents. This process provides the discipline necessary to ensure a successful development program while providing the flexibility necessary to allow integration of FDA regulatory processes.

Medical S&T drug development begins with a requirement to counter an existing threat to the warfighter. An ICD, developed by JRO-CBRND, should have been generated outlining, in broad terms, the capability required for the drug development. Drug research and development begins with pre-clinical (animal) testing. Pre-clinical testing involves a rigorous evaluation process of the drug characteristics, its stability, efficacy and manufacturing process. During this period, the JSTO is down selecting candidate drugs to arrive at one (1) or two (2) candidates that have demonstrated promising results. At this stage in the process, TRLs for the associated drug will have been established by the JSTO, with JPM concurrence. When the JSTO determines that the drug is ready for transition to the JPM for advanced development, the JSTO, in conjunction with the JPM, will request a MS A decision from the MDA. If milestone decision is approved, a complete technical package on the drug is compiled and submitted to the JPM at the time of transition. This package may become part of the JPM investigational new drug (IND) application packet that is submitted to the FDA.

The JPEO-CBD Chemical and Biological Medical Systems (CBMS) JPM, in conjunction with a Prime Systems Contractor (PSC) (if applicable), begins coordinating with the JSTO when candidates are in the DTO stage to gain technical familiarity with the program and to ensure that advanced development funding is aligned appropriately to support a candidate at MS B. This coordination also allows CBMS manufacturers to gain early visibility of the product candidate. The management lead for the program shifts to CBMS at MS

A, although both S&T and advanced development funds may be used during the Technology Development stage. This allows the manufacturer to engage with the JSTO early in the process. If multiple candidates are pursued, down selection occurs no earlier than the end of Phase 1 clinical trials that are conducted prior to MS B and program initiation. Once the program has transitioned, CBMS, in concert with a PSC (if applicable) will:

- Conduct Phase I, II, and III clinical trials as required
- Produce pilot and consistency lots
- Conduct definitive animal efficacy studies
- Submit the necessary regulatory documentation to obtain licensure to include the Biologics License Application (BLA) or New Drug Application (NDA)

MS B will be conducted once safety and efficacy data are available from the Phase I clinical trial and/or animal studies. MS C will be conducted once consistency lots have proven manufacturability in the case of a Low Rate Initial Production (LRIP) decision (for some programs) and licensure for a MS C Full Rate Production decision.

Medical Diagnostics S&T development follows along the same pathway as that of drug development with some differences. In diagnostic S&T development, pre-clinical and clinical trials are conducted without the need of an IND application. The clinical trial phase involves analysis of sensitivity and specificity of the diagnostics kits. This is accomplished by the JSTO via non-invasive human clinical testing. Transition to the JPM may occur during this period or the clinical testing phase may be jointly managed by the JSTO and the JPM. If clinical testing validates the diagnostics kits performance, a technical package will be compiled and submitted to the FDA for approval and fielding.

In general, medical technology transition begins with initial DoD/FDA discussions followed by S&T development and then a MS A decision. Subsequent work revolves around process development/manufacturing request for proposal (RFP): award process and manufacturing contract development; initiation of product development and manufacturing; animal safety studies; IND submission; phase1-III clinical trials, submission of the BLA or NDA, FDA licensure, and final transition to the warfighter. TREs to support JPM CBMS will be conducted on an as needed basis. The requirements for technology transition documentation (TDS, TES and TTAs) are applicable to JPM CBMS programs. Medical TRL definitions can be found in Appendix E.

Role of T&E in Technology Transition

Planning for CBDP T&E will begin at the earliest stages of the definition of user needs, science and technology, system requirements, development, and acquisition processes. System evaluators participate in the integrated concept team (ICT) review of the initial requirements documents when a new CBDP system or new technology is being considered for development.

The early involvement of the T&E community has become increasingly critical to ensure adequate data to support milestone decisions. Involvement of the T&E community in the test and evaluation strategy and coordination of the TTA is critical to overall success. In order to establish this early T&E involvement, the CBDP T&E Executive management funds are used to support early involvement of T&E in the technology development process.

The Joint T&E Executive supports and assists the JSTO and JPEO-CBD in the same manner as any joint program. Responsibilities include CBDP T&E policy, oversight and T&E issues resolution procedures. The Joint T&E Executive will also establish and review CBDP T&E procedures for transition efforts.

The T&E Executive must ensure that the T&E methodologies and capabilities are adequately identified in time to support TREs of transitioning technologies. In order to do this, the T&E Executive provides a T&E investment strategy and supports JPEO-CBD programs in the POM process to identify and fill T&E capability gaps for programs.

The T&E community independently assesses how well systems perform technically; how well the system fulfills documented requirements and whether systems are safe, operationally effective, suitable, and survivable for their intended use in military operations.

The T&E community does not establish system test criteria; these criteria are obtained from requirements documents and other sources reflecting system user needs, priorities, and operational concepts. The T&E community does define adequacy of test and thus the T&E capabilities required to perform testing. The input of the T&E community to developing test technologies along with system technologies is critical. The T&E community must have input into the process as well as clear and well defined guidance about how the system is expected to perform. The evolutionary acquisition concept challenges the requirements, acquisition, sustainment, and T&E communities to coordinate closely and continually when developing and testing phased or blocked programs to ensure

that the T&E community is aware of what will constitute a useful increment of capability. Only with this knowledge can the T&E community design appropriate tests.

The T&E community supports evolutionary acquisition by being continuously involved in the acquisition process, beginning with integrating T&E issues in the concept and technology development phase. JPMs can form a WIPT to assist with T&E issues. A WIPT can assist a pre-systems acquisition activity (e.g. ACTD, Advanced Technology Demonstration (ATD), or Joint Warfighter Experiment (JWE) that is likely to develop into an acquisition program.

Appendix A - Assigning TRLs within the CBDP

The methodology presented here represents a framework from which TRL assessments can be developed which is consistent across the CBDP community. A disciplined application of this methodology will result in TRL assessments that are credible and understandable regardless of which agency or group conducts the evaluation.

The assessment of TRLs is anything but a trivial process. The success and validity of the assessment depends on extensive knowledge concerning the development of the system, a thorough understanding of the technologies involved, a clear definition and understanding of the assessment purpose, the data available, and a good grasp of the TRL definitions. Absent any of these elements, the assessment results are suspect. The methodology presented here addresses the last element, dealing with the TRL definitions, by proposing a set of readiness variable descriptions, and a process for applying them, that can be used to guide the assessment to a defensible and repeatable conclusion. Continuing to develop and tailor those definitions to specific technology areas within the CBDP arena will only increase their utility and improve the validity of future TRL assessments.

By their nature, TRL assessments are somewhat subjective and vulnerable to differences of opinion concerning the status of a technology with respect to the TRL definitions. The readiness variables mitigate a portion of this subjectivity by offering some objective mileposts that further refine the basic definitions and can be tailored to the technology area of interest. Even so, the process will continue to involve individual judgments that will always be subject to argument or disagreement. This is one reason why TRL assessments should be conducted by more than one person. A group of stakeholders will bring different viewpoints and opinions to the process, making it stronger in the long run. The process outlined here provides a way to structure those judgments so that they can not only be defended in the face of criticism, but also ensures they address the needs of the decision makers involved.

TRLs are primarily a risk management tool. The JPM's decision to use a new technology in system development carries with it considerable cost and schedule risk, a defensible TRL process will clarify the JPM's risk mitigation strategy. If the technology is too immature, program costs can sky rocket and schedules can be delayed. GAO found in their review of 23 defense programs that where new technologies had matured to at least TRL 6 or higher, cost and schedule performance for the program were much improved over cases where more immature technologies were adopted. TRLs provide a structured, disciplined

approach to assessing maturity and a common framework with which to discuss maturity with program managers and decision makers.

While general statements concerning acceptable risk versus TRL are useful at a macro level, specific decisions on what constitutes acceptable risk for transition depend on the program, the technology involved, and the decision maker's risk profile. The middle ground of TRLs 4 – 6 constitute a gray area where risks may be acceptable or unacceptable depending on the specific situation. Managers have to weigh all the decision criteria, including the TRL of the technology in question to arrive at a decision.

In a July 2001 memorandum, the DUSD (S&T) officially endorsed the use of TRLs in new major acquisition programs, calling for TRL assessments for "critical technologies" identified prior to the start of engineering and manufacturing development and production. The Defense Acquisition Guidebook (DAG, 17 October 2004) discusses this requirement in general and provides definitions for TRLs at a system level.

TRLs 1 to 3 generally apply to technology development, and levels above this to the maturation of design application. In the case of technology development, TRL 1 represents basic science research and TRL 3 is the point where the performance attributes critical to use in practical applications are demonstrated. By definition, application concepts have not been explored in any detail at this stage.

Differentiation between TRLs 4 and 5 represents the transition from laboratory to 'real world' demonstration. In the case of a control system component, TRL 4 might be exemplified by artificial stimulation of response from the component (i.e. the representation of the system of which the component is part remains virtual). This can be compared with TRL 5 where the test component is demonstrated to work within a physical realization of the overall system (i.e. any stimulation is to the external system). The test component at TRL 5 might be representative of the technology or design proposed for the intended system application, however the overall demonstration system would not be representative (i.e. other physical elements within the demonstration would not replicate the fit or form of the intended application).

Above TRL 5, demonstration is of system prototypes or models (representative of form and function) with increasing similarity to the production system (TRL 8), culminating in completion of minor fixes on the final article at TRL 9, which will typically be cleared for operational use. While it is not always appropriate to develop a technology through every level, the risk associated with 'skipping' levels must always be balanced with the cost of taking a more controlled 'step by step' approach.

The TRL definitions contained in the DAG are constructed at the system level and are intended to apply to both hardware and software. Unfortunately, the application of these definitions to other than hardware can prove difficult. Recognizing this limitation, and taking advantage of the flexibility contained in the DAG language allowing supplementation of the basic definitions, the US Army Communications Electronics Command (CECOM) developed a set of alternative software definitions (Appendix C). Although there are some in the software development community who think the Army definitions may be too restrictive in places, they remain the only published attempt to apply the basic definitions to the area of software technology.

Missing in the standard definitions are references to non-system technologies, such as processes, methods, algorithms, or architectures. Non-system technologies can be of even more interest than hardware in the CB defense arena, where algorithms can play an especially important role. TRAs of these technologies require an additional set of definitions that address how their development and testing proceed (Appendix D).

The DAG leaves open the option to tailor the standard definitions to specific technology areas. This flexibility allows organizations to develop TRL definitions that reflect the unique characteristics and requirements of specific types of technologies. As an example, Appendix E includes TRL definitions that relate to drug, vaccines and medical equipment.

A major difficulty facing any organization tasked with assessing TRLs is the fact that the definitions blend together several aspects of readiness into each definition. Each step of the TRL scale is defined by a combination of the level of knowledge about the technology, the degree of integration achieved, the development environment, and the level of testing. This can lead to a dilemma of trying to decide which aspect takes precedence when assessing the maturity of a candidate technology. Take for example, the definition of TRL 8 found in the DAG:

TRL 8

Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications.

The definition requires the user to make judgments concerning the physical maturity of the system ("final form"), the development environment ("expected conditions"), and the type of testing conducted ("developmental testing").

Lacking specific guidance on how to weigh each of these aspects of readiness, users will typically default to basing the assessment primarily on the level of testing achieved or adopt an "all or nothing" approach that requires each aspect to be achieved in order to assign a specific TRL. At the higher TRLs (7, 8, and 9) this approach may be acceptable since the criteria are mutually supporting (i.e., satisfying one criteria usually means the others have been met as well) and easily recognized milestones such as developmental or operational tests characterize each level. Unfortunately, our focus is not usually on technologies this mature. Where managers need the most fidelity in applying the TRL definitions is exactly where the most ambiguity exists in the definitions (TRLs 1 to 6). Technologies at these levels of maturity are usually of most interest for transition or investment, but can often present conflicting pictures of maturity (see example below).

Ambiguous definitions:

A technology for point biological agent detection has been tested in a laboratory environment using what are still considered low fidelity components (not necessarily representative of final form, fit, or function) and agent simulants. As part of an examination of possible emerging technologies it is necessary to determine the system's TRL. As the process of assessing the technological readiness of the system proceeds there are many possible sources of confusion. First, by itself, the term "laboratory environment" could be consistent with TRLs 3, 4, 5, or 6. Similarly, "low fidelity components" could indicate TRLs 3, 4, or even 5 in some cases. The impact of the fact that the testing has been conducted with only simulants is hard to discern since the definitions do not refer to technology specific aspects of maturity.

As the example illustrates, one would be hard pressed to determine the TRL for this system using only the standard definitions without substantial interpretation and inference – not an ideal situation for a process that should deliver consistent, repeatable assessments independent of the individual conducting the assessment.

The second major dilemma one faces in assigning TRLs is at what level of system components to perform the assessment. There are basically two approaches that can be used: 1) perform the assessment at the system level, or 2) assess each critical component individually and use the individual TRLs to arrive at a system TRL. The first approach applies the definitions to the system as a whole and is probably the first methodology that new users of TRLs consider using. While it has definite disadvantages, one advantage of this approach is that the standard TRL definitions are written at the system level and most users are most familiar with them in this context. The second approach attempts to assign a TRL to each of the critical components of the system (which could themselves be considered

technologies) and then, using these individual evaluations, arrive at an overall system TRL. This approach also has several disadvantages, but one of its key advantages is that the decision maker is able to tailor the evaluation to address the technology components considered most important to the decision at hand. This is especially useful for programs like the TREs where there may be many disparate systems evaluated against a common set of criteria that may relate to only a subset of the technologies present in the candidate systems.

To mitigate some of the uncertainty and ambiguity inherent in this process, a methodology is needed that can resolve the ambiguities in the TRL definitions with consistency, that supports the goals of the JPEO-CBD and JSTO with respect to managing transition risk for emerging technologies, and is easy to apply and understand. This methodology needs to combine the best aspects of each approach described above, while mitigating to the extent possible the disadvantages of each.

Individual versus Team TRL Assessments

A key element affecting the credibility of a TRL assessment is who conducts it. There is nothing that says an individual familiar with the technology and the TRL process can't be assigned to conduct the evaluation alone. While this may be convenient in terms of resources used, it may not be the best solution to achieve the most robust and credible assessment.

Regardless of how objective and specific the readiness definitions become, they remain subject to interpretation. These interpretations will always be influenced by personal backgrounds, experiences, and biases that will affect the outcome of the evaluation. One way to mitigate these biases is to have more than one person involved in the assessment. By bringing together individuals of differing backgrounds to evaluate the readiness of a technology, a consensus opinion can be reached that blends those biases, resulting in a stronger evaluation. If the evaluation team includes the principal stakeholders for the technology, as well as representatives of the acquisition community, the credibility of the assessment is reinforced.

M E T H O D O L O G Y

A review of the published information concerning TRL assessments reveals little in the way of specific guidance that can be directly applied to the needs of the JPEO-CBD with respect to the conduct of TREs. Several organizations and individuals have published papers or PowerPoint® presentations about their

specific applications, providing useful insights into the process and the potential challenges one faces in assessing any technology's maturity. [2, 6, 10, 11, 12] Their usefulness is limited, however, by the very characteristic that prompted their creation in the first place – the need to tailor and customize the process to meet the unique needs of a specific technology area. This customization applies not only to the definitions themselves, but to their application as well – thus, the need for a methodology that addresses the specific needs of the CBDP community.

The Technology Readiness Assessment Deskbook describes an assessment methodology that requires the JPM and JSTO to identify critical technologies for evaluation as part of the decision process for moving a system on to the next stage of development. These critical technologies are typically at the sub-system level. Each critical technology is evaluated separately for maturity and assigned a TRL – no attempt is made to assign an overall TRL to the system at this stage. The decision about whether a system is ready to move to MS B or C is made by the Component Acquisition Executive (with concurrence from the DUSD(S&T)) assessing all the information provided in the TRA.

By contrast, the TREs typically evaluate technologies that would represent the sub-systems or critical technologies in the larger context of the TRA (see Example 1). To further complicate matters, the TRE technologies may themselves consist of sub-technologies that may be at various levels of maturity (See Example 2).

Example 1

The purpose of TRE-2 was to examine the readiness of trigger technologies for a networked, point biological detector. Where a TRA for this system would examine its readiness to progress to MS B or C, and in the process assign TRLs to identified critical technologies, the TRE's purpose was to identify candidate technologies to accomplish specific functions in the objective system. Thus, a critical technology for the TRA becomes the evaluation focus for the TRE.

Example 2

There are several sub-systems of a networked, point detector that could be considered critical in the context of a TRA. Besides the trigger sub-system, these could include: the collection sub-system, the network sub-system, the trigger/detector algorithm, and command and control software. The candidate technologies for TRE-2 all consisted of various combinations of these sub-systems at differing levels of maturity.

Assigning TRLs at the sub-system level would seem to be a good model for the TREs; if a methodology were available for arriving at an overall decision concerning technology readiness similar to the process used for a TRA (decision maker reviews all available information and makes a determination concerning the system's readiness to move forward). Unfortunately, the scope of the TREs makes this part of the TRA methodology unwieldy for the JPEO-CBD to implement.

An alternative approach would be to assign TRLs directly at the system level. The difficulty with applying the definitions at the system level is that the sub-systems can be at various levels of maturity raising the question as to which definition best represents the aggregate system maturity.

Comparing the two approaches, one finds advantages and disadvantages to each. In the end, however, by assigning TRLs at the sub-system level, one is addressing readiness at the functional level for the system. This approach allows flexibility in steering the assessment focus to the most important technology components. This is not to say that the sub-system approach does not present any challenges. The dilemma still remains how to blend the readiness of the various components into a single readiness level for the system.

The TRL methodology consists of four basic steps:

- Understand how the technology will be used (the program requirements).
- Identify the critical technologies consistent with the proposed use.
- Assess the readiness of each critical technology using the appropriate readiness variables.
- Using the results from step 3, determine the overall system TRL.

The readiness variables are fundamental to this process, but they still don't represent a complete solution. First, how does one blend the variables together to arrive at an estimate of maturity? Second, for systems that may contain multiple critical technologies, how do we use the individual maturity evaluations to estimate the maturity of the system as a whole? To begin to answer these questions we start by examining the steps above.

Identify the Critical Technologies

Presumably, a TRL evaluation is undertaken to establish a system's level of maturity relative to a specific purpose. The reason this is so important is that a given technology may exhibit differing levels of maturity for different applications. For example, if we are interested in networked, point detectors, the critical technologies might be the detection algorithms, the detection hardware, and the network sub-system (hardware and software). A candidate system may also

include a collection sub-system, identification sub-system, or any number of other "technologies" that contribute to its function but are not considered critical for the application we are considering. By identifying the critical technologies with respect to the evaluation purpose, we begin to prioritize the effort and shape the evaluation to reflect those priorities.

Assess the Readiness of Each Critical Technology

Having identified the critical technologies, the next step is to evaluate their maturity using the appropriate readiness variables. This process requires collecting detailed information about the system such as: analytical studies that have been conducted; testing that may have been conducted, including who conducted it, where it was conducted, the test environment, and the results; the maturity of the hardware; the level of integration of the components; the level of development of system software; the maturity of system algorithms; and, any other aspect of the system that may be important for evaluating the readiness variables. How this evaluation is conducted is discussed in the next section.

Determine the Overall System TRL

Once the TRLs for the critical technologies have been determined, the final step is to determine the overall system TRL. For a system that consists of a single critical technology, this step is straightforward – the system TRL is simply the TRL of the critical technology. For a system that consists of more than one critical technology, to the lowest TRL of a critical technology component of the system is the overall system TRL.

READINESS VARIABLES

Depending on the nature of the technology involved, there are a number of variables of readiness that need to be considered as one evaluates a technology: Knowledge, Form – Fit – Function, Level of Development, Integration, Testing, and Environment.

Knowledge refers to the level of understanding the developer has about the technology of interest and its intended application. Levels of understanding range from a basic grasp of the underlying scientific principles involved to a complete understanding of the operational environment and interfaces necessary for a particular application.

Form/Fit/Function refers to system packaging and function. It measures how close the system is to its final configuration. Form/Fit/Function only applies to hardware.

Level of Development applies to algorithms and software-based technologies. It refers to how far along the development path the technology has progressed.

Integration is another readiness variable that applies to algorithm and software technologies. It measures the achieved level of integration with system.

Testing refers to the level or type of testing that has been performed. Levels of testing range from exploratory experiments and/or simulation-based testing of breadboard systems to full-up operational testing of final system configurations. The testing variable also includes whether T&E capabilities, methods, models, and tools exist for adequate operational testing, and how the existence of the needed infrastructure affects the TRL supported

Environment refers primarily to the testing and operating environments the technology has experienced. Environments can vary considerably, but generally range from desktop/academic settings to full operational missions.

Table 1 shows where each of these variables is used to estimate technology readiness.

Table 1. Readiness Variable use versus technology category

	Hardware	Software	Algorithms	System
Knowledge	X	X	X	
Form-Fit-Function	X			
Level of Development		X	X	
Integration		X	X	X
Testing	X	X	X	X
Environment	X	X	X	X

Each of these variables can be defined and scaled to correlate with the standard TRL definitions. They can also be tailored to the specific technology or application under consideration. This means we can develop variable descriptions that are consistent with CBDP systems and address the aspects of readiness most important to an evaluation of these technologies (e.g., hardware, software, algorithms). These descriptions are the foundation of the evaluation of technology readiness and are based on analysis and interpretation of the standard TRL definitions.

Each variable description consists of discrete steps representing increasing levels of maturity for that variable, as well as the corresponding TRL based on the standard definitions. There are three sets of descriptions for hardware, software and algorithms. The hardware descriptions are presented here and will be used throughout the remainder of the document to explain and illustrate the evaluation methodology.

Table 2. Variable Descriptions for Level of Knowledge

Knowledge	Highest TRL Supported
Basic scientific principles observed	1
Science known to extent that mathematical and/or computer models and simulations are possible	1
Rigorous analytical studies confirm basic principles	2
Physical laboratory experimental evidence confirms basic principles	3
Possible application exists	3
Paper studies show that application is feasible	3
Laboratory experiments verify application is feasible	4
Overall system requirements for end user's application are known	5
System interface requirements known	5
Operating environment for eventual system known	9

Table 3. Variable Descriptions for Level of Form/Fit/Function

Form/Fit/Function	Highest TRL Supported
No system components, just basic laboratory research equipment to verify physical principles	2
Ad hoc and available laboratory components are surrogates for system components	4
Some special purpose components combined with available laboratory components	5
Components are functionally compatible with operational system	6
Components are representative of production components	7
Components are form, fit, and function compatible with operational system	9

Table 4. Variable Descriptions for Testing.

Testing	Highest TRL Supported
None	2
Analytical experiments	5
Component tests	6
Developmental testing	7
DT&E complete	8
OT&E demonstrates that system is capable of performing mission requirements	9

Table 5. Variable Descriptions for Environment.

Environment	Highest TRL Supported
"Back of envelope" environment	1
Desktop environment	2
Academic environment	3
Laboratory environment, simulants only	4
Laboratory environment, simulants with potential interferants	6
Laboratory environment, live agent with or without interferants	6
Outdoor environment, simulants only	7
Outdoor environment, simulants with potential interferants	8
Outdoor environment, live agent with or without interferants	9
Operational environment	9

The descriptions in Tables 2 – 5 should be considered as representative of the various levels of maturity and not necessarily exact descriptions to be used for every technology. In other words, they should not be considered a checklist, but rather serve as guidelines to help estimate the maturity of a technology. They are, however, assumed to build upon each other to represent increasing levels of readiness. For example, when evaluating the level of knowledge achieved, the last entry in Table 2 assumes that all of the steps above it or their equivalent have been accomplished.

These tables illustrate that even at the most basic level there is still some ambiguity inherent in trying to define levels of readiness. At each step beyond the first, the description can support multiple TRLs depending on the status of other variables. Even so, these descriptions provide a means for more consistent interpretation of the TRL definitions, as well as an opportunity to tailor those definitions to a particular technology area.

ASSESSING CRITICAL TECHNOLOGIES

Each critical technology is evaluated independently using the readiness variable descriptions. As each variable is evaluated, the result is one or more supported TRLs for each area. The overall TRL for the technology is the highest common supported level across all of the variables. Table 6 presents a hypothetical example for a hardware-based technology. The highest common supported level is a TRL of five, thus this technology would be assessed to be at TRL 5 with respect to hardware development.

Table 6. Individual technology assessment example

Readiness Variable	Level Achieved	TRL Supported
Knowledge	Operating environment for eventual system known	1, 2, 3, 4, 5, **6**, 7, 8, 9
Form/Fit/Function	Components are functionally compatible with operational system,	1, 2, 3, 4, 5, **6**
Testing	Component tests	1, 2, 3, 4, **5**, 6
Environment	Laboratory environment, simulants with potential interferants	1, 2, 3, 4, 5, **6**, 7

If there are no other technology components of interest, the assessment may conclude at this point with the system being assessed at TRL 5. If, however, there are other critical technologies or other components associated with this technology (detection algorithms for example), the process must be repeated for each component before an overall TRL can be determined.

SYSTEM TRL ASSESSMENT

The overall system TRL is a function of both individual component readiness, as well as the maturity of the integration of those components. How complex this evaluation becomes, depends in part on the complexity of the system. There are three readiness variables that pertain to the system as a whole: Testing, Integration, and Environment. Testing and Environment are similar to what has been presented previously except now we are looking at testing of the integrated system. Tables 7, 8, and 9 present the descriptions of the readiness variables for this aspect of the evaluation.

Table 7. Variable descriptions for System Testing

Testing	Highest TRL Supported
None	2
Analytical experiments	5
Component tests	6
Developmental testing	7
DT&E complete	8
OT&E demonstrates that system is capable of performing mission requirements	9

Table 8. Variable Descriptions for System Integration

Integration	Highest TRL Supported
No attempt at integration; still trying to see whether individual parts of the technology work	1
Paper studies indicate that system components ought to work together	1, 2
Laboratory experiments with available components show that they work together (lab kludge)	3
Available components assembled into system breadboard	4
Interfaces between components/subsystems are realistic (Breadboard with realistic interfaces)	5
Fidelity of system mock-up improves from breadboard to brassboard	6
Laboratory system is high-fidelity functional prototype of operational system	7
Prototype improves to pre-production quality	8
System is form, fit, and function design for intended application and weapon system platform	8, 9
System has been installed and deployed in intended weapon system platform	9

Table 9. Variable Descriptions for System Environment

Environment	Highest TRL Supported
"Back of envelope" environment	1
Desktop environment	2
Academic environment	3
Laboratory environment, simulants only	4
Laboratory environment, simulants with potential interferants	6
Laboratory environment, live agent with or without interferants	6
Outdoor environment, simulants only	8
Outdoor environment, simulants with potential interferants	9
Outdoor environment, live agent with or without interferants	9
Operational environment	9

The system TRL can be no higher than the lowest TRL of the component critical technologies. Thus, if a system consists of three critical technologies, A, B, and C at TRLs 6, 7, and 9 respectively, the system TRL can be no higher than TRL 6. It could, however, be lower than TRL 6, depending on the level of integration,

testing, and environment for the system as a whole. Table 10 presents an example situation for the three-technology system described above. Even though the individual components are more mature, the overall TRL would be TRL 5, since this is the highest common TRL supported by the system readiness variables.

Table 10. System Assessment Example

Readiness Variable	Level Achieved	TRL Supported
Integration	Interfaces between components/subsystems are realistic (Breadboard with realistic interfaces)	1, 2, 3, 4, **5**
Testing	Component tests	1, 2, 3, 4, **5**, 6
Environment	Laboratory environment, simulants with potential interferants	1, 2, 3, 4, **5**, 6

Another situation could arise where there are multiple critical technologies but one technology is "more critical" than the others. This could happen, for instance, when the decision maker is particularly interested in a single aspect of a system such as agent detection, but other aspects are also critical (the network sub-system for instance). For example, using the same three-technology system, if technology B is the priority, the system TRL could be as high as TRL 7 if the system readiness variables support this level. The ceiling for the system TRL is driven by the TRL of the "most" critical technology, even if the other "critical" technologies are less mature.

Why not just average the sub-system TRLs?

Averaging the sub-system TRLs would appear to be a simple, straightforward method for determining a system TRL. At first, it seems like a simple way to combine the TRLs from the various sub-systems to arrive at a TRL for the system as whole. The flaw in this logic is that the TRL numbers do not really represent a simple ordinal scale, but are actually category labels representing maturity definitions that have specific criteria associated with them. Thus, it is not necessarily true that a system that consists of two sub-systems, one at TRL 6 and one at TRL 8, would have an overall TRL of 7. This would only be true if the system demonstrated a level of integration, plus testing in an appropriate environment, that justifies a TRL 7. It would be more accurate to say that the system could have a TRL no higher than six or eight, depending on which sub-system represents the critical technology. A separate evaluation of maturity at the system level, looking at integration, testing and environment is necessary to determine whether the system TRL is at or below the critical technology TRL.

A CASE STUDY

The following example is based in part on TRE 2. It provides some insight into the challenges that can present themselves in the course of a TRL assessment.

BACKGROUND

The Federal Business Opportunities Vendors Notice for TRE 2 announced that the US Army would be sponsoring a TRE for "…automatic, light weight, networked and non-networked, biological point detection technologies…". Eventually, 12 systems, representing a wide variety of technologies, intended missions, and maturity, were evaluated for their potential to act as triggers for a system such as the Joint Biological Tactical Detection System. Part of the TRE was assigning TRLs to each of the participating systems.

CRITICAL TECHNOLOGIES

The first step was to identify the critical technologies. The starting point for this determination is the mission statement. From that statement and additional analysis, the technology sub-systems of interest were determined to be: detection/identification sub-systems, network sub-systems, trigger/cue sub-systems, collection sub-systems, and command and control software. The trigger/cue sub-system and the detection/identification sub-system were expanded to also include the associated algorithms for each.

Because there are multiple technology sub-systems, the next step was to prioritize those technologies from most to least important. In this case, the trigger/cue sub-system and detection/identification sub-system were considered the most important (choice depends on the type of system), and became the critical technologies for the TRL assessment. Each of the technology sub-systems was assigned a TRL, but the system TRL was based on the readiness of the system as a whole plus the maturity of the critical technology.

SYSTEM DESCRIPTION

The example system is a biological trigger consisting of a trigger/cue sub-system (including a trigger algorithm), a collection sub-system, a network sub-system, and command and control software. The first challenge is collecting information of sufficient detail to be able to make assessments of maturity using the readiness variables. This information can come from many sources, with the primary source likely to be the vendor. Depending on the time and other resources available, this information can be collected in many ways including questionnaires, interviews, phone conversations, and email. Despite best efforts, the level of completeness and fidelity of the information is likely to be far from ideal. The sidebar below summarizes the available information for the example system and is representative of the level of completeness one can expect, especially for TREs. (Although based on an actual participating system from TRE-2, the description has been

edited to protect potential proprietary information. Some familiarity with bio-detection technology is assumed.)

Example System Description

General Information: The system is the result of three years of company-funded development and the underlying technology is patent pending.

Trigger/Cue Sub-System: The trigger/cue sub-system technology is based on Ultra-Violet Laser Induced Fluorescence. A single laser diode is used to induce fluorescence and elastic scatter that are measured using three Photo Multiplier Tubes. Particles are interrogated one at a time after being drawn into the device through an aerosol concentrator.

Trigger Algorithm: The system uses two fluorescence channels plus an elastic scatter channel to size classify particles and determine the presence of biological material. Particles are classified into small, medium and large size bins. For each bin, an independent fluorescence threshold is established to determine whether the particle has significant biological content. This is all accomplished in real time. The count of particles detected per second, as well as the count of biological particles per second in each size bin is recorded. A moving average is computed from the instantaneous particle counts. An instantaneous biological fraction signal is derived for each size bin by taking the ratio of the biological count rate to the particle count rate for that bin. Also, a smoothed biological fraction signal is derived for each size bin by taking the ratio of the moving average biological count to the moving average particle count for each bin. A system alarm is declared when the smoothed biological fraction exceeds a fixed threshold.

Collection Sub-System: The system uses a new collection sub-system that utilizes high flow axial vane fans as an aerosol impactor. The fans are less than one inch square and can be placed in-line with the aerosol output or can have their own intake. When an alarm occurs the fans are turned on and collection is initiated. An independent laboratory has reported collection efficiencies of better than 80% for BG spores. Extraction of the sample is achieved by applying liquid to the fan assembly. The fans are considered disposable.

Detection/Identification Sub-System: None.

Network Sub-System: Network concepts have been developed and the system is physically capable of being networked, but has not been formally tested. Network detection algorithms have not been developed.

Command and Control Sub-System: The command and control software is mature and functional.

Testing: The system has begun testing for military, facility security, and mail security applications at representative locations. Integration of new components of the collection sub-system has only recently been completed and the components have not been previously tested together. Trigger algorithms continue to be developed and tested in a controlled laboratory environment, as well as field locations. Testing has only been accomplished using BWA simulants and a limited number of interferants.

A N A L Y S I S

Starting with the least important technology first, the command and control software is characterized as "…mature and functional." By itself this would appear to argue for a fairly high TRL – TRL 7 to TRL 9. Going through each of the software readiness variables we find that the actual maturity may not be quite this high. The level of Knowledge supports up to TRL 8; Function Development supports TRL 9; Integration supports up to TRL 8; Environment supports up to TRL 6; and Testing supports up to TRL 7. The command and control software is, therefore at TRL 6.

The collection sub-system is made up of relatively mature components, but its integration into the example system is relatively recent and has undergone only limited laboratory testing to date. Knowledge supports up to TRL 9. Form/Fit/Function supports up to TRL 7. Testing supports up to TRL 6. Environment also supports up to TRL 6. The collection sub-system TRL is, therefore, TRL 6.

The network sub-system is very immature and incomplete with respect to the requirements of the objective system. The level of Knowledge supports a TRL 2; Form/Fit/Function supports up to TRL 5; Testing supports up to TRL 5; and Environment supports up to TRL 3. The highest common TRL is, therefore, TRL 2 – beyond the idea stage, but still in the concept development process. The trigger/cue sub-system is based on UVLIF technology and hardware, which is fairly mature conceptually. Knowledge therefore supports a TRL up to TRL 9. Form/Fit/Function of the components is relatively far along after three years of development and supports a TRL 7. Testing of the components is still in the developmental test stage and therefore supports TRL 7 as well. The test environment has been primarily laboratory, with simulants and some interferants, so the Environment would support TRL 6. The trigger/cue sub-system TRL is, therefore, TRL 6.

The trigger algorithms are the real innovation of the system and the heart of the technology. By definition, the algorithms have experienced many of the same tests and environments that the hardware has undergone. The difference, and the reason that the algorithm maturity may be different than the hardware used to collect the data they process, is that the variables that define their readiness are different than those of the hardware. In some cases the descriptions are the same as for hardware technologies (Environment), in some they address the same issue but use different descriptions (Knowledge and Testing), and for others they are unique to algorithms (Development and Integration).

In this case, the level of Knowledge about the principles behind the algorithms supports up to TRL 9; the Environment supports TRL 6; the level of Development supports up to TRL 9; Integration is at TRL 8; and Testing supports TRL 7. The algorithms are, therefore, at TRL 6.

Summarizing:

Technology Sub-system	TRL
Trigger/cue hardware	6
Trigger algorithm	6
Collection	6
Network	2
Command & Control	6

The overall system TRL can be no higher than TRL 6, based on the level of maturity of the critical technology (trigger/cue plus trigger algorithm). It can, however, be less, depending on the level of integration achieved and the level of system testing completed. All of the recent testing has been at the system level, so Environment and level of Testing are the same as noted earlier and support a TRL 6. The system is in an advanced prototype stage in terms of form-fit-function and supports an Integration TRL of 7. The overall system TRL, assuming the trigger/cue technology is the highest priority, is therefore TRL 6. If the network technology were determined to be the priority, the system would be at TRL 2, based on the maturity of that sub-system.

Appendix B – TRL Definitions

Tables B1 and B2 come from the TRA Handbook and show the standard DAG definitions for each TRL, along with additional supporting information intended to make their application easier.

Table B1. TRL Definitions, Descriptions, and Supporting Information.

TRL	Definition	Description	Supporting Information
1	Basic principles observed and reported	Lowest level of technology readiness. Scientific research begins to be translated into applied research and development. Examples might include paper studies of a technology's basic properties.	Published research that identifies the principles that underlie this technology. References to who, where, when.
2	Technology concept and/or application formulated	Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative, and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.	Publications or other references that outline the application being considered and that provide analysis to support the concept.
3	Analytical and experimental critical function and/or characteristic proof of concept	Active research and development is initiated. This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.	Results of laboratory tests performed to measure parameters of interest and comparison to analytical predictions for critical subsystems. References to who, where, and when these tests and comparisons were performed. Aspects of technology, including predictive algorithms, aspects to be simulated and variables upon which predictions and simulations depend, have been identified. Aspects of the technology are identified that drive test technology needs.
4	Component and/or breadboard validation in [a] laboratory environment	Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared to the eventual system. Examples include integration of "ad hoc" hardware in the laboratory.	System concepts that have been considered and results from testing laboratory-scale breadboard(s). References to who did this work and when. Provide an estimate of how breadboard hardware and test results differ from the expected system goals. Data available that includes measures of physical variables affecting performance and relating the performance of components to systems," to the Supporting Information column.
5	Component and/or breadboard validation in [a] relevant environment	Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so they can be tested in a relevant environment. Examples include "high-fidelity" laboratory integration of components.	Results from testing a laboratory breadboard system that are integrated with other supporting elements in a simulated operational environment. How does the "relevant environment" differ from the expected operational environment? How do the test results compare with expectations? What problems, if any, were encountered? Was the breadboard system refined to match the expected system goals more nearly? Data available that includes measures of

TRL	Definition	Description	Supporting Information
			performance that usually includes the use of live agents
6	System/subsystem model or prototype demonstration in a relevant environment	Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high-fidelity laboratory environment or in [a] simulated operational environment.	Results from laboratory testing of a prototype system that is near the desired configuration in terms of performance, weight, and volume. How did the test environment differ from the operational environment? Who performed the tests? How did the test compare with expectations? What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before moving to the next level? Technology-specific test technology and methodologies have been developed. Initial modeling and simulation indicate successful technology performance. CB agent simulants identified. Initial safety testing completed.
7	System prototype demonstration in an operational environment	Prototype near, or at, planned operational system. Represents a major step up from TRL 6, requiring demonstration of an actual system prototype in an operational environment such as an aircraft, vehicle, or space. Examples include testing the prototype in a test bed aircraft.	Results from testing a prototype system in an operational environment. Who performed the tests? How did the test compare with expectations? What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before moving to the next level? Demonstration of a model indicating affects of environmental variables completed. Safety data and report completed. Performance validated using CB simulants.
8	Actual system completed and qualified through test and demonstration	Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications.	Results of testing the system in its final configuration under the expected range of environmental conditions in which it will be expected to operate. Assessment of whether it will meet its operational requirements. What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before finalizing the design? Full technology, component, subsystem or system testing with live agent/simulant. Results match performance predictions from simulations. System field testing using simulants.
9	Actual system proven through successful mission operations	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation. Examples include using the system under operational mission conditions.	Operational test and evaluation reports.

Table B2. Additional TRL Terms and Definitions.

Term	Definition
Breadboard	Integrated components that provide a representation of a system/subsystem and that can be used to determine concept feasibility and to develop technical data. Typically configured for laboratory use to demonstrate the technical principles of immediate interest. May resemble final system/subsystem in function only.
High Fidelity	Addresses form, fit, and function. [A] High-fidelity laboratory environment would involve testing with equipment that can simulate and validate all system specifications within a laboratory setting.
Low Fidelity	A representative of the component or system that has limited ability to provide anything but first-order information about the end product. Low-fidelity assessments are used to provide trend analysis.
Model	A functional form of a system, generally reduced in scale, near or at operational specification. Models will be sufficiently hardened to allow demonstration of the technical and operational capabilities required of the final system.
Operational Environment	Environment that addresses all the operational requirements and specifications required of the final system to include platform/ packaging.
Prototype	A physical or virtual model used to evaluate the technical or manufacturing feasibility or military utility of a particular technology or process, concept, end item, or system.
Relevant Environment	Testing environment that simulates the key aspects of the operational environment.
Simulated Operational Environment	Either (1) a real environment that can simulate all of the operational requirements and specifications required of the final system or (2) a simulated environment that allows for testing of a virtual prototype; used in either case to determine whether a developmental system meets the operational requirements and specifications of the final system.

Appendix C – Software TRL Definitions

The US Army Communications Electronics Command (CECOM) developed a set of alternative TRL definitions for software –based systems that take advantage of the DAG language that allows organizations to augment or tailor the standard definitions to their unique needs. These definitions were first published outside CECOM in a report from the Carnegie Mellon Software Engineering Institute in September 2002 ("Using Technology Readiness Levels Scale to Support Technology Management in the DoD's ATD/STO Environments, A Findings and Recommendations Report Conducted for Army CECOM"). Navy software TRL definitions are almost identical to those listed below and can be found on the Office of Naval Research website at:

http://www.onr.navy.mil/fncs/auto_ops/trl_software.asp

Table C1. Software TRL Definitions.

TRL	Definition	Description	Supporting Information
1	Basic principles observed and reported.	Lowest level of software technology readiness; a new software domain is being investigated by the basic research community. This level extends to the development of basic use, basic properties of software architecture, mathematical formulations and general algorithms	Basic research activities, research articles, peer-reviewed white papers, point papers, early lab model of basic concept may be useful for substantiating the TRL level
2	Technology concept and/or application formulated.	Once basic principles are observed practical applications can be invented. Applications speculative and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies using synthetic data.	Applied research activities analytic studies, small code units, papers comparing competing technologies
3	Analytical and experimental critical function and/or characteristic proof of concept	Active research and development is initiated. The level at which scientific feasibility is demonstrated through analytical and laboratory studies. This level extends to the development of limited functionality environments to validate critical properties and analytical predictions using non-integrated software components and partially representative data.	Algorithms run on a surrogate processor in a laboratory environment, instrumented components operating in laboratory environment, laboratory results showing validation of critical properties
4	Module and/or subsystem validation in a laboratory environment, i.e. software prototype development environment	Basic software components are integrated to establish that they will work together. They are relatively primitive with regard to efficiency and robustness compared with the eventual system. Architecture development initiated to include interoperability, reliability, maintainability, extensibility, scalability, and security issues.	Advanced Technology Development, Standalone prototype solving a synthetic full-scale problem, or standalone prototype processing fully representative data sets.

TRL	Definition	Description	Supporting Information
		Emulation with current/ legacy elements as appropriate. Prototypes developed to demonstrate different aspects of eventual system.	
5	Module and/or subsystem validation in a relevant environment	Level at which software technology is ready to start integration with existing systems. The Prototype implementations conform to target environment / interfaces. Experiments with realistic problems. Simulated interfaces to existing systems. System software architecture established. Algorithms run on a processor(s) with characteristics expected in the operational environment.	System architecture diagram around technology element with critical performance requirements defined, Processor selection analysis, Sim/Stim Laboratory buildup plan. Software placed under configuration management. COTS/GOTS in the system software architecture are identified.
6	Module and/or subsystem validation in a relevant end-to-end environment	Level at which the engineering feasibility of a software technology is demonstrated. This level extends to laboratory prototype implementations on full-scale realistic problems in which the software technology is partially integrated with existing hardware/software systems.	Results from laboratory testing of a prototype package that is near the desired configuration in terms of performance including physical, logical, data and security interfaces. Comparisons to tested environment to operational environment analytically understood. Analysis and test measurements quantifying contribution to system-wide requirements such as throughput, scalability and reliability. Analysis of human-computer (user environment) begun.
7	System prototype demonstration in an operational high fidelity environment	Level at which the program feasibility of a software technology is demonstrated. This level extends to operational environment prototype implementations where critical technical risk functionality is available for demonstration and test in which the software technology is well integrated with operational hardware/software systems.	Critical technological properties are measured against requirements in a simulated operational environment
8	Actual system completed and mission qualified through test and demonstration in an operational environment	Level at which a software technology is fully integrated with operational hardware and software systems. Software development documentation is complete. All functionality tested in simulated and operational scenarios.	Published documentation Product technology refresh build schedule Software resource reserve measured and tracked
9	Actual system proven through successful mission proven operational capabilities	Level at which a software technology is readily repeatable and reusable. The software based on the technology is fully integrated with operational hardware/software systems. All software documentation verified. Successful operational experience. Sustaining software engineering support in place. Actual system.	Production configuration management reports Technology integrated into a reuse “wizard”, out year funding established for support activity

Appendix D – Algorithm TRL Definitions

The definitions presented here were developed in conjunction with TRE-2 and represent a first attempt to develop measures of maturity for this important technology area in the CBDP arena.

Table D1. Algorithm TRL Definitions.

TRL	Definition	Description
1	Basic principles observed and reported.	Basic properties of algorithm defined.
2	Technology concept and/or application formulated.	Algorithm coded. Experiments with synthetic data. Example: algorithm tested with data containing only signal, no noise.
3	Analytical and experimental critical function and/or characteristic proof of concept.	Limited functionality implementations. Experiments with small representative data sets. Scientific feasibility fully demonstrated. Example: algorithm fed more complicated (still synthetic) data representing intended target signals.
4	Component and/or breadboard validation in laboratory environment.	Experiments with full-scale problems or data sets in a laboratory environment. Example: algorithm presented with "real" data (simulants only at this stage) obtained from hardware in a clean environment.
5	Component and/or breadboard validation in relevant environment.	Algorithm fully integrated with hardware. Test of algorithm in a relevant simulated environment using "live" data. Begin development of signature database. Example: algorithm presented with "real" data (primarily simulants, but may include actual targets) in an environment that includes possible interferants. May be conducted in a controlled environment such as an aerosol chamber or breeze tunnel.
6	System/subsystem model or prototype demonstration in a relevant environment.	Algorithm tested in a representative model or prototype system, which is well beyond that of TRL 5. Signature database substantially complete for initial targets. Example: algorithm presented with more complex situations such as multiple targets and interferants. May be conducted in a controlled environment such as an aerosol chamber or breeze tunnel.
7	System prototype demonstration in an operational environment.	Algorithm demonstrated in an operational environment. Represents a major step up from TRL 6, requiring demonstration of an actual system prototype in an operational environment. Example: algorithm demonstrated in a system prototype in an operational environment that includes all initial targets and expected interferants.
8	Actual system completed and qualified through test and demonstration.	Algorithm has been proven to work in its final form and under expected conditions. Signature database for initial targets (not simulants) complete. In almost all cases, this TRL represents the end of true algorithm development..
9	Actual system proven through successful mission operations.	Actual application of the algorithm in its final form and under mission conditions, such as those encountered in operational test and evaluation.

Appendix E – Medical TRL Definitions

Medical-related items require TRL definitions and descriptions that are appropriate to the technologies upon which they are based and that account for the statutes and regulations that govern their development and use. In recognition of these factors, the U.S. Army Medical Research and Material Command (USAMRMC) took the initiative to establish appropriate definitions, descriptions, and processes in the context of military medical research and development and the statutory and regulatory requirements under the stewardship of the FDA.

USAMRMC's TRL definitions for medical equipment and pharmaceuticals represent one of the most comprehensive efforts to date to customize the standard TRL definitions to a particular technology area. These efforts are indicative of what is required to make the definitions relevant for technologies that have unique requirements and milestones that must be met before they can be considered "mature" enough for fielding or transition.

Table E1. Medical TRL Definitions.

TRL	DoD Description (DAG, Oct 2004)	Medical Description (Oct 2004)
1. Basic principles observed and reported.	Lowest level of technology readiness. Scientific research begins to be translated into applied research and development. Examples might include paper studies of a technology's basic properties.	Earliest level of technology readiness. Active monitoring of scientific knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new technologies
2. Technology concept and/or application formulated.	Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.	Focus efforts on practical applications based on basic principles observed. Generation of scientific "paper studies" that review and generate research ideas, hypothesis, and experimental designs for addressing the related scientific issues.

TRL	DoD Description (DAG, Oct 2004)	Medical Description (Oct 2004)
3. Analytical and experimental critical function and/or characteristic proof of concept.	Active research and development is initiated. This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.	Research, data collection, and analysis begin in order to: test hypothesis; explore alternative concepts; identify and evaluate critical technologies and components; and research and eventual development of candidate countermeasure(s). Conduct non-clinical studies to support models based on presumed battlefield conditions.
4. Component and/or breadboard validation[1] in laboratory environment.	Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared to the eventual system. Examples include integration of "ad hoc" hardware in the laboratory.	Laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous experimental design. Exploratory study of critical technologies for effective integration into candidate(s). Assess safety and efficacy utilizing animal model(s). Propose assays, surrogate markers, and endpoints to be used during non-clinical and clinical studies to evaluate and characterize candidate(s).
5. Component and/or breadboard validation[2] in relevant environment.	Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so it can be tested in a simulated environment. Examples include "high fidelity" laboratory integration of components.	Conduct non-clinical research studies involving data collection and analysis in well-defined systems with highly characterized lots of candidate(s) produced and further development of selected candidates. Develop a robust and reproducible manufacturing process amenable to current good manufacturing practice (cGMP). Qualify assays for potency, purity, identity and quality. Qualify surrogate markers for efficacy in animal models
6. System/subsystem model or prototype demonstration in a relevant environment.	Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high-fidelity laboratory environment or in simulated operational environment.	Manufacture, release and stability test good manufacturing practice (GMP) pilot lots Conduct Good Laboratory Practice (GLP) safety studies Prepare and Submit IND Conduct Phase 1 clinical trial

[1] Not "validation" as defined by FDA. FDA-type validations will be done at TRL 6-8 and are needed for licensure.

[2] Not "validation" as defined by FDA. FDA-type validations will be done at TRL 6-8 and are needed for licensure.

TRL	DoD Description (DAG, Oct 2004)	Medical Description (Oct 2004)
7. System prototype demonstration in an operational environment.	Prototype near, or at, planned operational system. Represents a major step up from TRL 6, requiring demonstration of an actual system prototype in an operational environment such as an aircraft, vehicle, or space. Examples include testing the prototype in a test bed aircraft.	Conduct Phase 2 clinical trial. Establish final dose, dose range, schedule, and route of administration. Data collected, presented, and discussed with FDA at meeting (Type B). Clinical endpoints and supporting animal test plans agreed to by FDA. Complete process validation and initiate consistency lot production.
8. Actual system completed and qualified through test and demonstration.	Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications.	Complete production & testing of consistency lots. Conduct Phase 3 clinical trials, if applicable. Submit BLA/NDA to FDA Obtain FDA approval.
9. Actual system proven through successful mission operations.	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation. Examples include using the system under operational mission conditions.	Post licensure/approval use of product. Fulfill post-licensure commitments, if required.

Appendix F – Readiness Variables

H A R D W A R E :

Knowledge (Hardware)	Highest TRL Supported
Basic scientific principles observed	1
Rigorous analytical studies confirm basic principles	2
Physical laboratory experimental evidence confirms basic principles; Possible application exists	3
Laboratory experiments verify application is feasible	4
Overall system requirements for end user's application are known	5
System interface requirements known	7
Operating environment for eventual system known	9

Form-Fit-Function (Hardware)	Highest TRL Supported
No system components, just basic laboratory research equipment to verify physical principles	2
Ad hoc and available laboratory components are surrogates for system components	4
Some special purpose components combined with available laboratory components	5
Components are functionally compatible with operational system	6
Components are representative of production components	7
Components are form, fit, and function compatible with operational system	9

Testing (Hardware)	Highest TRL Supported
None	2
Analytical experiments	5
Component tests	6
Developmental and environmental testing	7
DT&E demonstrates that the system is capable of meeting mission requirements	8
OT&E demonstrates that system is capable of performing mission requirements	9

Environment (Hardware)	Highest TRL Supported
"Back of envelope" environment	1
Academic environment	3

Laboratory environment, simulants only	4
Laboratory environment, simulants with potential interferants	5
Laboratory environment, live or inactivated agent with or without interferants	6
Outdoor environment, simulants only	6
Outdoor environment, simulants with potential interferants	7
Outdoor environment, live or inactivated agent with or without interferants	8
Operational environment	9

S O F T W A R E :

Knowledge (Software)	Highest TRL Supported
Know what software needs to do in general terms	2
Have some concept in mind that may be realizable in software	2
Have an idea that captures the basic principles of a possible algorithm	2
Initial analysis shows what major functions need to be done in software	2
Initial analysis gives some idea of what software architecture will look like	2
Analysis provides detailed knowledge of specific functions software needs to perform	2
Know what hardware software will be hosted on	2
Know what output devices are available	3
Outline of software algorithms available	3
Know what software is presently available that does similar task (Inventory completed)	3
Know limitations of presently available software (Analysis of current software completed)	4
Analysis of data requirements and formats completed	4
Analysis of internal interface requirements completed	5
External interfaces described as to source, format, structure, content, and method of support	5
Inventory of external interfaces completed	7
Analysis of timing constraints completed	7
Analysis of database structures and interfaces completed	9

Development (Software)	Highest TRL Supported
None	2
Software architecture defined in terms of major functions to be performed	2
Preliminary algorithm development completed	3
Software programming language selected	3
Formal software test/inspection protocol defined	3
Algorithms converted to pseudocode	4
Requirements for each function established	4
Coding of individual functions/modules completed	9

Integration (Software)	Highest TRL Supported
None	2
Existing software examined for possible reuse	4
Functions integrated into modules	5
"Alpha" version software has been released	6
"Beta" version software has been released	9

Testing (Software)	Highest TRL Supported
None	2
Metrics established	3
Designs verified through formal inspection process	4
Individual functions tested to verify that they work	5
Individual modules and functions tested for bugs	5
Individual modules tested to verify that the module components (functions) work together	6
Verification, Validation and Accreditation (VV&A) initiated	6
Each software/system interface tested individually under stressed and anomalous conditions	6
VV&A in process with the verification step that software specifications are met completed	7
VV&A validation step completed, software works in real world	7
VV&A accreditation step completed, software authorized for use in intended system	7
DT&E completed, software meets specifications	8
OT&E completed, software system is operational	9

Environment (Software)	Highest TRL Supported
"Back-of-the-envelope" concept	1
Academic environment	3
Individual functions or modules demonstrated in a laboratory environment	4
Integration of modules/functions demonstrated in a laboratory environment	5
Representative software system or prototype demonstrated in a laboratory environment	6
Fully integrated software prototype demonstrated in actual or simulated operational environment	7
Software qualified through test and evaluation in actual system (DT&E completed)	8
Actual mission software "flight proven" through successful mission operations (OT&E completed)	9

A L G O R I T H M S :

Knowledge (Algorithms)	Highest TRL Supported
Basic scientific principles observed	1
Rigorous analytical studies confirm basic principles	2
Analysis provides detailed knowledge of specific functions algorithm needs to perform	4
Implementation software identified	5
Internal and external interfaces identified	6
Experimental evidence confirms basic principles	9

Development (Algorithms)	Highest TRL Supported
None	1
Algorithm logic "sketched out"	2
Preliminary algorithm development started	3
Software programming language selected	4
Algorithm development complete	6
Algorithm converted to pseudocode	7
Algorithm coding complete	9

Integration (Algorithms)	Highest TRL Supported
None	2
Stand alone	4
Working version available on developmental platform	5
Algorithm integrated with prototype system	7
Algorithm integrated with operational system	9

Environment (Algorithms)	Highest TRL Supported
"Back of envelope" environment	1
Academic environment	3
Laboratory environment, simulants only	4
Laboratory environment, simulants with potential interferants	5
Laboratory environment, live or inactivated agent with or without interferants	6
Outdoor environment, simulants only	6
Outdoor environment, simulants with potential interferants	7
Outdoor environment, live or inactivated agent with or without interferants	8
Operational environment	9

Testing (Algorithms)	Highest TRL Supported
None	2
Experiments with synthetic data to verify basic functionality	3
Experiments with small scale operationally representative data sets (synthetic)	4
Experiments with full scale data sets (synthetic)	5
Initial experiments with limited-scale "live" data	6
Experiments with full scale live data sets	7
DT&E demonstrates that system meets procurement specifications	8
OT&E demonstrates that system is capable of performing mission requirements	9

S Y S T E M :

Integration	Highest TRL Supported
No attempt at integration; still trying to see whether individual parts of the technology work	1
Paper studies indicate that system components ought to work together	2
Laboratory experiments with available components show that they work together (lab kludge)	3
Available components assembled into system breadboard	4
Interfaces between components/subsystems are realistic (Breadboard with realistic interfaces)	5
Fidelity of system mock-up improves from breadboard to low-fidelity prototype	6
Laboratory system is high-fidelity functional prototype of operational system	7
Prototype improves to pre-production quality	8
System is form, fit, and function design for intended application and weapon system platform	9
System has been installed and deployed in intended weapon system platform	9

System Environment	Highest TRL Supported
"Back of envelope" environment	1
Academic environment	3
Laboratory environment, simulants only	4
Laboratory environment, simulants with potential interferants	5
Laboratory environment, live or inactivated agent with or without interferants	6
Outdoor environment, simulants only	6
Outdoor environment, simulants with potential interferants	7
Outdoor environment, live or inactivated agent with or without interferants	8
Operational environment	9

Testing	Highest TRL Supported
None	2
Analytical experiments	5
Component tests	6
Developmental and environmental testing	7
DT&E demonstrates that the system is capable of meeting mission requirements	8
OT&E demonstrates that system is capable of performing mission requirements	9

Appendix G - Manufacturing Readiness Levels

Table G1. Manufacturing Readiness Level Definitions.

TRL	MRL	MRL Definition	Description	Key Manufacturing Issues	Acquisition Phase
1	**1**	NA			
2	**2**	NA			
3	**3**	Manufacturing concepts identified	Identification of current manufacturing concepts or producibility needs based on laboratory studies.	-Have critical manufacturing processes been identified? -What are the initial assumptions and understanding regarding availability of manufacturing capabilities? - Is there a similar manufacturing process in use? If so, what can be learned from the process? -Will a manufacturing process or processes have to be developed or can an existing process be modified?	Pre-concept refinement
4	**4**	Laboratory manufacturing processes identified	Key processes identified and assessed in laboratory. Risk mitigation strategies identified to address manufacturing/producibility shortfalls. Preliminary Cost as an Independent Variable (CAIV) targets set and cost drivers identified.	-What are the key properties of the end item that are critical to maintain expected functionality/performance (materials, signal, orientation, interface characteristics, noise levels etc)? -What is the range of tolerances for the key properties and subsystems to retain functionality/performance? - How is this information being tracked/documented? -Have subcontract components been included as part of the analysis? -Do available manufacturing capabilities support the key performance parameters? Has this been tested or is it assumed? -Has a risk management strategy been identified to address manufacturing /producibility of critical manufacturing processes? -Have preliminary Cost as an Independent Variable (CAIV) targets been set and cost drivers identified?	Concept refinement leading to a Milestone A decision
5	**5**	Manufacturing process development	Trade studies and laboratory experiments result in development of key manufacturing processes and initial sigma levels needed to satisfy CAIV targets. Preliminary manufacturing assembly sequences identified. Process, tooling, inspection, and test equipment in development. Significant	-Have key manufacturing process steps been outlined? -Has it been demonstrated that critical parameters can be measured or controlled to the required level? -Is there an initial manufacturing plan on sources of key components? -Can a cost be associated with each critical component with reasonable confidence or will additional information/development be required? If not, what is the plan to acquire the information?	

TRL	MRL	MRL Definition	Description	Key Manufacturing Issues	Acquisition Phase
			engineering and design changes. Quality and reliability levels not yet established. Tooling and machines demonstrated in the laboratory. Physical and functional interfaces have not been completely defined.	-Do initial cost estimates show the need for potential manufacturing process tradeoffs?	
6	**6**	Critical manufacturing Processes demonstrated	Critical manufacturing processes initially demonstrated for the relevant environment (laboratory or simulated operational environment). Initial goals established for yields. Process and tooling generally mature. Frequent design changes still occur. Investments in machining and tooling identified. Quality and reliability levels identified. Design to cost goals identified.	-Have the critical manufacturing processes been shown to produce a product of acceptable performance -Has the selected manufacturing process demonstrated the same level of performance over multiple (dozens, hundreds, thousands) production items? -Is the process well documented? -What tooling still needs to be developed? What is the level of risk in developing this tooling? -What analysis was used to develop predicted quality levels/yields? Is this an acceptable risk or is further production testing required? -How were manufacturing costs identified and what were the assumptions? Do they require additional development and refinement of manufacturing processes to meet goals? Are they based on technology breakthroughs?	Technology Development (TD) leading to a Milestone B decision
7	**7**	Prototype manufacturing system	Prototype system built based on mature tooling. Initial sigma levels established, based on yields and quality data from laboratory or simulations. Design changes decrease significantly. Process tooling and inspection and test equipment demonstrated in pre-production environment. Manufacturing processes well understood. CAIV and design to cost goals validated.	-For quality levels, has the characteristics of an acceptable product/component been clearly defined for initial production (critical characteristics and limits)? -What process inputs affect product quality and how are they being controlled? Has full-scale production equipment been proven to produce an acceptable component within targeted quality levels? -Have the CAIV and design to cost goals been validated.	System Development and Demonstration (SDD)
8	**8**	Manufacturing process maturity demonstration	Manufacturing processes demonstrate		SDD, leading to a Milestone C decision and LRIP

TRL	MRL	MRL Definition	Description	Key Manufacturing Issues	Acquisition Phase
			acceptable yield and producibility levels for pilot line, low rate initial production (LRIP), or similar item production. All design requirements satisfied. Manufacturing processes well understood and controlled to 4-sigma or appropriate quality level. Minimal investment in machine and tooling (should have completed demonstration in at least a low rate production environment). Cost estimates less than 125 percent of cost goals (e.g., design-to-cost and CAIV goals met for LRIP).		
9	**9**	Manufacturing processes proven	Manufacturing line operating at desired sigma or similar quality level. Stable design and production. All manufacturing processes controlled to 6-sigma or appropriate quality level. Cost estimates less than 110 percent of cost goals or meets cost goals (e.g., CAIV and design-to-cost goals met).		Production, deployment, and support

Appendix H - Technology Transition Agreement Format

TECHNOLOGY TRANSITION AGREEMENT OF (INSERT S&T TECHNOLOGY NAME AND CONTROL# HERE) TO (INSERT ACQUISITION PROGRAM OF RECORD NAME HERE)

1. **Description of Technology or Capability to be Delivered**

Responsible party: JSTO. Briefly describe what the S&T activity intends to develop for transition to the acquisition program. Include capability delivery dates

2. **Target Acquisition Program**

Responsible party: JPEO-CBD. Provide a brief description of the acquisition program to receive the technology/product. Include:

a. Major program objectives.
b. Current phase of the acquisition life cycle.
c. Projected initial operational capability date.

3. **Acquisition Program Technology Need**

Responsible party: JPEO-CBD. Identify the technology needs of the acquisition program that S&T is expected to provide. Briefly describe the benefit that the technology/product will bring to the acquisition program:

a. Relate the benefit to the ICD, CDD, CPD, etc.
b. Include need dates for specific capabilities.

4. **Integration Strategy**

Responsible party: JPEO-CBD. Describe the process for integrating the technology/product into the acquisition program. Include the following elements of acquisition strategy:

a. Evolutionary acquisition, block upgrade, etc.
b. Required contractor-to-contractor agreements
c. Acquisition Program Element (PE) numbers funding the transition
d. Annual PE funding levels committed to the transition program
e. Transition Fiscal Year (FY)
f. Statement conveying the level of commitment. For example: Intent: "Upon successful demonstration of key performance requirements (exit criteria), JPM XXX (acquisition program office) may integrate XXX (product performer is delivering)

into XXX (acquisition program that will integrate deliverable) commencing in FYXX (transition year) under PE XXXXXXX Project XXXX (FYDP budget profile)

5. Points of Contact

Identify personnel responsible for acquisition project management, S&T Technology Manager, and financial point of contact (POC):

a. Project Manager POC information
b. Technology Manager (Principal Investigator) POC information
c. Financial POC information
d. ICT manager POC information
e. T&E POC information

6. Requirements

Responsible party: JPEO-CBD in coordination with JRO-CBRND.
Identify the governing source of the capability requirement: the ICD, CDD, or other official reference documenting the capability need and date approved.

7. Test and Evaluation Strategy (See also the Test and Evaluation Strategy section on p.18)

Responsible party: JSTO in coordination with JPEO-CBD, Joint T&E Executive

a. Test Methodology development to be accomplished.
b. Concept of employment
c. Early operational assessment opportunity
d. Key performance parameters
e. Test Infrastructure to be provided
f. T&E POC and contact information

8. Technical Details and Programmatics

Responsible party: JSTO

a. Technology – Current Status

Status Summary. Summarize current state of development. Identify:

i. Primary areas where additional development is required.
ii. Estimate of current TRL.

b. Risk Analysis. Prioritize and discuss major areas of technical risk. Identify planned mitigation activities to address technical risk (e.g, producibility, affordability, sustainability).

Top Risks	Brief Descriptions	Mitigation Strategy

c. Technology Development Strategy (See also the TDS section for content, page 17)

Outline planned approach. Include:

i. Efforts required beyond those currently underway.
ii. Integration plans if multiple projects are planned.
iii. Form, fit, and function
iv. Interoperability
v. Planned ATD or ACTD developments, if applicable.

9. Exit Criteria

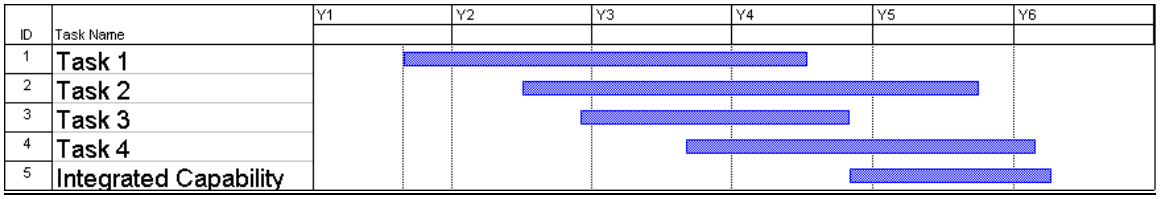
Responsible party: JPEO-CBD. Key technical measures of readiness.
Identify quantifiable criteria that will be used to assess effectiveness and suitability of the technology/product development effort.
Provide:

a. Conditions under which technology/product will be tested/demonstrated prior to delivery to acquisition.
b. Current performance of the technology/product.
c. Minimum acceptable performance threshold.
d. Desired final goal/objective.
e. Estimate of the transition TRL.
f. Establish criteria for development of the receiver operating characteristics (ROC) curve and spider chart prepared for the Assessment Panel. These criteria will include definitive, complete, and measurable parameters including all applicable key performance parameters.

Attribute/ Parameter	Current	Minimum Threshold	Objective

10. Program Plan

Responsible party: JSTO. Show major activities/efforts planned for the technology/product development with milestones. Include both S&T and acquisition tasks/elements.



11. Transition Program Element Funding

Transition PE	FY03	FY04	FY05	FY06	PE Total
0604***N	$K	$K	$K	$K	$K
FY Total	$K	$K	$K	$K	$K

12. Signatures

Acquisition Project Manager — Date
JPM XXX

S&T Project Manager — Date
JSTO DTRA-CB CAPO XXX

Appendix I – RDT&E Budget Activities

The RDT&E budget activities are broad categories reflecting different types of RDT&E efforts. The definitions are provided below.

Budget Activity 1: Basic Research

Basic research is systematic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind. It includes a scientific study and experimentation directed toward increasing fundamental knowledge and understanding in those fields of the physical, engineering, environmental, and life sciences related to long-term national security needs. It is farsighted high payoff research that provides the basis for technological progress. Basic research may lead to: (a) subsequent applied research and advanced technology developments in Defense-related technologies, and (b) new and improved military functional capabilities in areas such as communications, detection, tracking, surveillance, propulsion, mobility, guidance and control, navigation, energy conversion, materials and structures, and personnel support. Program elements in this category involve pre-Milestone A efforts.

Budget Activity 2: Applied Research

Applied research is systematic study to understand the means to meet a recognized and specific need. It is a systematic expansion and application of knowledge to develop useful materials, devices, and systems or methods. It may be oriented, ultimately, toward the design, development, and improvement of prototypes and new processes to meet general mission area requirements. Applied research may translate promising basic research into solutions for broadly defined military needs, short of system development. This type of effort may vary from systematic mission-directed research beyond that in Budget Activity 1 to sophisticated breadboard hardware, study, programming and planning efforts that establish the initial feasibility and practicality of proposed solutions to technological challenges. It includes studies, investigations, and non-system specific technology efforts. The dominant characteristic is that applied research is directed toward general military needs with a view toward developing and evaluating the feasibility and practicality of proposed solutions and determining their parameters. Applied Research precedes system specific technology investigations or development. Program control of the Applied Research program element is normally exercised by general level of effort. Program elements in this category involve pre-Milestone B efforts, also known as Concept and Technology Development phase tasks, such as concept

exploration efforts and paper studies of alternative concepts for meeting a mission need.

Budget Activity 3: Advanced Technology Development

This budget activity includes development of subsystems and components and efforts to integrate subsystems and components into system prototypes for field experiments and/or tests in a simulated environment. ATD includes concept and technology demonstration of components and subsystems or system models. The models may be form, fit and function prototypes or scaled models that serve the same demonstration purpose. The results of this type of effort are proof of technological feasibility and assessment of subsystem and component operability and producibility rather than the development of hardware for service use. Projects in this category have a direct relevance to identified military needs. Advanced Technology Development demonstrates the general military utility or cost reduction potential of technology when applied to different types of military equipment or techniques. Program elements in this category involve pre-Milestone B efforts, such as system concept demonstration, joint and Service-specific experiments or Technology Demonstrations and generally have Technology Readiness Levels of 4, 5, or 6. Projects in this category do not necessarily lead to subsequent development or procurement phases, but should have the goal of moving out of Science and Technology (S&T) and into the acquisition process within the future years defense program (FYDP). Upon successful completion of projects that have military utility, the technology should be available for transition.

Budget Activity 4: Advanced Component Development and Prototypes

Efforts necessary to evaluate integrated technologies, representative modes or prototype systems in a high fidelity and realistic operating environment are funded in this budget activity. The ACD&P phase includes system specific efforts that help expedite technology transition from the laboratory to operational use. Emphasis is on proving component and subsystem maturity prior to integration in major and complex, systems and may involve risk reduction initiatives.

Program elements in this category involve efforts prior to Milestone B and are referred to as advanced component development activities and include technology demonstration. Completion of Technology Readiness Levels 6 and 7 should be achieved for major programs. Program control is exercised at the program and project level. A logical progression of program phases and development and /or production funding must be evident in the FYDP.

Budget Activity 5: System Development and Demonstration

SDD programs have passed Milestone B approval and are conducting engineering and manufacturing development tasks aimed at meeting validated requirements prior to full-rate production. This budget activity is characterized by major line item projects and program control is exercised by review of individual programs and projects. Prototype performance is near or at planned operational system levels. Characteristics of this budget activity involve mature system development, integration and demonstration to support Milestone C decisions and conducting live fire test and evaluation (LFT&E) and initial operational test and evaluation (IOT&E) of production representative articles. A logical progression of program phases and development and production funding must be evident in the FYDP consistent with the Department's full funding policy.

Budget Activity 6: RDT&E Management Support

This budget activity includes research, development, test and evaluation efforts and funds to sustain and/or modernize the installations or operations required for general research, development, test and evaluation. Test ranges, military construction, maintenance support of laboratories, operation and maintenance of test aircraft and ships, and studies and analyses in support of the RDT&E program are funded in this budget activity. Costs of laboratory personnel, either in-house or contractor operated, would be assigned to appropriate projects or as a line item in the Basic Research, Applied Research, or Advanced Technology Development program areas, as appropriate. Military construction costs directly related to major development programs are included.

Budget Activity 7: Operational Systems Development

This budget activity includes development efforts to upgrade systems that have been fielded or have received approval for full rate production and anticipate production funding in the current or subsequent fiscal year. All items are major line items projects that appear as RDT&E Costs of Weapon System Elements in other programs. Program control is exercised by review of individual projects. Programs in this category involve systems that have received Milestone C approval. A logical progression of program phases and development and production funding must be evident in the FYDP, consistent with the Department's full funding policy.

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